# **EXHIBIT DX1**

TO DECLARATION OF BENJAMIN W. HULSE IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SAMSUN LAMPOTANG, PH.D.

## CASE 0:15-md-02666-JNE-DTS Doc. 912-1 Filed 10/03/17 Page 2 of 260

Confidential - Subject to Protective Order

		Page 1
1	UNITED STATES DISTRICT COURT	
2	DISTRICT OF MINNESOTA	
3		-
4	In Re:	
5	Bair Hugger Forced Air Warming	
6	Products Liability Litigation	
7		
8	This Document Relates To:	
9	All Actions MDL No. 15-2666 (JNE/FLM)	
10		-
11		
12		
13	DEPOSITION OF SAMSUN LAMPOTANG, Ph.D.	
14	VOLUME I, PAGES 1 - 310	
15	AUGUST 11, 2017	
16		
17		
18	(The following is the deposition of SAMSUN	
19	LAMPOTANG, Ph.D., taken pursuant to Notice of Taking	
20	Deposition, via videotape, at the DoubleTree by	
21	Hilton, 2101 Dixie Clipper Drive, in the City of	
22	Jacksonville, State of Florida, commencing at	
23	approximately 8:35 o'clock a.m., August 11, 2017.)	
24		
25		

Page 2		Page 4
1 APPEARANCES: 2 On Behalf of the Plaintiffs:	1	PROCEEDINGS
3 Genevieve M. Zimmerman MESHBESHER & SPENCE, LTD.	2	(Lampotang Exhibit 1 marked for
4 1616 Park Avenue	3	identification.)
Minneapolis, Minnesota 55404	4	(Witness sworn.)
Gabriel Assaad 6 KENNEDY HODGES	5	SAMSUN LAMPOTANG,
4409 Montrose Boulevard  7 Suite 200	6	Called as a witness, being first
Houston, Texas 77006	7	duly sworn, was examined and
On Behalf of the Defendants:	8	testified as follows:
Deborah E. Lewis 10 BLACKWELL BURKE P.A.	9	EXAMINATION
431 South Seventh Street 11 Suite 2500	10	BY MS. ZIMMERMAN:
Minneapolis, Minnesota 55415	11	Q. Good morning, Dr. Lampotang.
ALSO PRESENT:	12	A. Good morning.
Ronald M. Huber, Videographer	13	Q. My name is Genevieve Zimmerman, we met just
14 EXAMINATION INDEX	14	a moment ago. I'm one of the lawyers that has been
15 WITNESS EXAMINED BY PAGE Dr. Lampotang Ms. Zimmerman 4	15	appointed by the Court to represent the nearly 3,000
16 Ms. Lewis 299 17 EXHIBIT INDEX	16	people who have brought claims in in this
EXHIBIT DESCRIPTION PAGE 18 Lampotang	17	multidistrict litigation proceeding. We're going to
1 Handwritten billing/meeting notes, 4 19 6 pgs.	18	go over some kind of ground rule ground rules to
2 Subpoena to Lampotang, 8 pgs. 34 20 3 Report of Samsun Lampotang, Ph.D., 61	19	begin with.
17 pgs. 21 4 Samsun Lampotang, Ph.D., Materials 66	20	First of all, did I pronounce your name
Considered, 3 pgs.  22 5 Samsun Lampotang, Ph.D., Materials 91	21 22	correctly? A. Yes.
Considered, with handwritten notes,	23	Q. Dr. Lampotang? And is that what you prefer
6 Curriculum Vitae, Samsun Lampotang, 97	24	to be addressed as?
24 Ph.D., 119 pgs. 7 Photo of Bair Hugger label, 1 pg. 217 25	25	A. You can call me Sam.
	23	71. 1 od can can me gam.
Page 3		Page 5
1 8 Excerpt, Table 2: MINIMUM 247	1	· ·
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Page 6

my question, first of all, is just to talk about some of the rules that we're going to have today. So maybe we'll back up and we'll go there.

You've had your deposition taken before so you know that I'm going to be asking you a series of questions today, and you'll be providing answers, and the court reporter here, Debby, will be taking down both my questions and your answers. And we will make her job much easier if we try to wait for each other to stop speaking before -- before we -- before you answer a question, for example.

12 A. Okay.

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Q. Just do your best to try to wait for me to stop asking a question. And likewise I will do my very best to wait until you have finished your answer before I start another answer.

Is that fair?

- A. Yes.
- Q. Okay. And you're doing a good job right now listening and -- and providing verbal answers. It's difficult for the court reporter to take down huh-uh's and uh-huh's, so to keep a clear transcript it's best if you can say "yes" or "no" and then we can work on a qualifier if that's necessary.

Is that fair?

1 A. -- in the plaintiffs, --

- O. All right.
  - A. -- in the patients who are in this case.
- 4 Q. Okay. Do you know how the plaintiffs have 5 alleged those infections have been caused?

Page 8

Page 9

- A. The plaintiffs themself?
- Q. Yeah. Do you --

I mean, do you have an understanding about the nature of the claimed defect in the Bair Huggers?

- A. Some of them, yes.
- Q. All right. And what is your understanding?
- A. One is --

Can you repeat the question, please?

Q. Sure. Do you --

Do you know what the plaintiffs are saying is wrong with the Bair Hugger machine that it would cause infections?

- 18 A. The plaintiffs, or the -- or the plaintiffs' 19 counsel?
- 20 Q. For purposes today we're basically the same, 21 so.
  - A. Okay. Yeah. I believe that there is some question about the -- the need for a -- a filter that has a higher rating, there is the -- there is the
- 25 allegation that the Bair Hugger causes infection, and

Page 7

A. Yes.

- Q. Okay. Now as I ask questions, if -- if you have any trouble understanding me or you're not sure what I'm asking, will you please let me know so I can do my best to rephrase the question?
- A. Yes.
- Q. Okay. And if I -- if you -- if you answer my question I'm going to assume that you understood the question. Is that fair?
  - A. Yes.
- Q. Okay. And you understand that you have been 12 offered as an expert witness on behalf of 3M and Arizant Corporation; is that right?
  - A. Yes.
  - Q. Okay. What is your understanding of the nature of the claims that the plaintiffs have brought?
  - A. Well that the Bair Hugger has caused infection in those plaintiffs.
  - Q. And do you, as you sit here today, do you know what the plaintiffs allege is wrong with the Bair Hugger?
  - A. Right, and I want to -- to restate my previous answer, that -- that -- so the plaintiffs allege that the Bair Hugger has caused infection --

Q. Okay.

1 there is the allegation that the current filter is not 2 optimal, or -- or is not doing its job.

Q. Okay. Do you understand that there are allegations that the Bair Hugger machine is contaminated, as well?

A. Would that --

Is your question based on me seeing whatever the -- the paperwork is related to the Court? Because I didn't see that, so I don't think I can answer your question, because I didn't --

(Outside interruption.)

MS. ZIMMERMAN: Sorry about that.

13 A. Yeah, so let me say that again.

So I -- I'm not sure I understand your question fully. I'm not briefed in all the paperwork about what the formal --

Q. Sure. Let me try to ask it a little different.

So have you been provided a copy of the plaintiffs' Complaint in this case?

- A. No.
  - Q. Okay. Have you been provided --
- 23 A. Actually I don't even understand the
- question. I'm sorry. What does "complaint" mean, 24
- 25 because I don't do this for a living.

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Page 10

O. Sure. 1

- 2 A. So "complaint" may mean something completely
- 3 different --
- Q. All right. 4
- 5 A. -- in legalese compared to...
- 6 Q. Right.

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- A. Yeah.
- 8 Q. So a Complaint is a -- a document that we
- submit to the Court and to a person that you might
- sue, a person or a company, that outlines what you
- think they did wrong, and why you think that that has 11 caused you some damage. 12

And that's a gross oversimplification, but that's essentially what a Complaint is.

- A. Okay.
- Q. The plaintiffs in this case have submitted a Complaint which is, I don't know, close to a hundred pages long, outlining the facts as we believe them to be and why we believe that 3M and Arizant are negligent and otherwise responsible for causing these
- injuries. The question that I'm trying to ask you, I guess, is: As you sit here today, do you know what the mechanism of defect is that the plaintiffs have alleged in this case?

Q. And what have you been asked to do in this 1 2 case?

Page 12

Page 13

- A. I've been asked to review the case.
  - Q. All right. And --

So in my job as one of the lawyers appointed 6 by the Court on behalf of the 3,000 or so people that

7 have cases filed so far, I have both an opportunity

- 8 and an obligation today to ask you questions about the
- 9 report that you prepared which details your opinions
- 10 that you intend to offer at trial in this matter. And
- the reason for that is so that we can understand what 11
- your opinions are, and what the basis is for your 12
- 13 opinions so we can understand if they are reliable and
- if they will ultimately assist the Court, and maybe 14
- the jury in this case, in deciding issues related to 15 the plaintiffs' claims. 16

So when you were asked to become involved in this case, was a -- were you presented with a specific question, or just a pile of documents to look at?

- 20 A. I was -- I was asked to -- to review, to
- 21 look at documents, yeah.
- 22 Q. Okay. Did --
- 23 A. And -- Yeah.
  - Q. Did you do any independent research?
- 25 A. Yes.

Page 11

- A. "The mechanism of defect."
- 2 Q. Yes.
- 3 A. Is that, again, a legal term, or? 4 (Interruption by the reporter.)
- 5 A. Is "mechanism of defect" a legal term? I'm
- 6 not sure why.
  - Q. Not specifically.
- 8 A. Okay. Well I guess I answered that earlier,
- 9 which is that the filter is -- is not -- is not -- the
- allegation that the filter is not working as it 10 11 should.
- 12 Q. Okay. Are there any other things that you believe the plaintiffs have alleged are defective in the Bair Hugger? 14
  - A. I've seen some studies that indicate that there are infectious organisms.
    - O. Inside the machine?
- 18 A. Inside the machine.
- 19 Q. Okay.
- 20 A. Or -- Or rather, that the exit from the Bair
- Hugger hose they were able to culture things out of 21 22
  - it, so I should rephrase that.
- 23 Q. Okay.
- 24 A. That's -- That's one study I think I
- 25 remember.

- Q. All right. And how did you do the 1 2 independent research?
- 3 A. I did some online research, I did some
- 4 literature search, I --
  - Q. Do you remember what you searched for?
- 6 A. Yeah. I search about the Bair Hugger and 7 forced-air warming.
  - Q. Did you search anything else?
- 9 A. Yeah. As I read the literature, I -- I
  - talked with -- no, I e -- I -- actually, yes, I did
- 10 talk with clinical engineering about what are their 11
  - practices.
    - Q. Practices regarding what?
- A. Cleaning equipment. 14
- 15 Q. Regarding cleaning the Bair Hugger, or cleaning any equipment? 16
  - A. Actually cleaning the inside of equipment.
- 18 Q. Did you --

Were you speaking with the clinical

- 20 engineering folks at Shands?
- A. At the University of Florida. 21
- 22 Q. "Yes"?
- 23 A. Yes.
- 24 Q. Okay. And who was that that you spoke with?
- 25 A. I actually don't know his -- his name. He's

Page 14 Page 16 a cli -- He's a clinical bio -- I'm sorry. He's a 1 Well generally dust is not clean, right, -biomedical engineer, and I gave a course that he 2 O. Umm-hmm. attended, and I walk into the office because I had 3 A. -- so. Q. Do you talk about dust particles? always been concerned about the dust that gathers 4 5 5 inside equipment. A. No. I just talked about dust. 6 Q. That's something you've been concerned 6 Q. All right. You think it's fair to call dust 7 about? 7 a particle? 8 8 A. The -- The particle, is this in general A. Yeah, like on the motherboard, because I've 9 opened it before, and -- to do some repairs, and... 9 English, or are we talking of? Q. So you met with -- you met with the clinical 10 Yeah, in general I think we could say dust 10 engineering gentleman who you don't remember at 11 11 is a particle. Shands. Did you take notes during this meeting? 12 12 Q. All right. Does --13 A. No. I just talked with him. 13 Does dust contain bacteria? 14 Q. All right. How long did the meeting last? 14 A. It is possible. A. I would say maybe five, ten minutes. Q. All right. Does it contain anything else 15 15 Q. All right. And what did you learn? that would be troubling to you? 16 16 17 A. I learned that generally they don't open 17 THE WITNESS: I think that's my phone. equipment in the OR to -- to periodically, on a I'll just put it on airplane mode. [Phone 18 18 routine basis, clean the equipment. vibrating.] Sorry about that. 19 19 20 Q. All right. And you --20 Q. That's okay. 21 A. If the equipment needs repair, they open it 21 So you said the dust can contain bacteria. sometimes in the OR, but then they vacuum it. 22 Can it contain anything else? 22 23 Q. The inside of whatever machine? 23 THE WITNESS: I'm sorry. Let me just put 24 A. Because they're already in there, then they 24 it on airplane mode. Thank you. 25 25 A. Yeah. vacuum it. Page 15 Page 17 Q. Okay. 1 Q. So dust can contain bacteria; correct? 1 A. If it's portable, they take it out of the OR 2 2 A. Yes. and they blow -- they use compressed air to blow it. 3 Q. All right. Why -- Why is bacteria something 4 Q. Blow it clean? 4 that you care about in an operating room? 5 A. Blow it clean. 5 MS. LEWIS: Objection, form. 6 6 MS. ZIMMERMAN: That's a good... Q. All right. 7 A. The one exception is the -- the fiberoptic 7 Q. Is -- Is bacteria something that you are 8 8 where they -- they clean it from outside. concerned about in an operating room? 9 Q. Fiberoptic? 9 A. Bacteria would be a concern in an operating A. Fiberoptic lights. 10 10 room, that's why we have aseptic procedures, but I Q. Okay. And where do the fiberoptic lines go? think it's -- it is important to establish that it is 11 11 12 A. They're in the OR. 12 very difficult to have zero bacteria. 13 Q. All right. Are they connected to a 13 Q. And I'm sure that we'll get to that particular piece of equipment? throughout the course of today. But why -- why are 14 14 A. Oh, I'm sorry. You -- It's my accent. you concerned about bacteria in an operating room? 15 15 "Lights," --16 MS. LEWIS: Objection, form. 16 O. "Lights." A. The -- Well bacteria could be a source of 17 17 18 A. -- not "lines." 18 infection. Q. Okay. "Lights." All right. 19 19 Q. And that's one of the reasons you don't want 20 You mentioned that you have always been 20 bacteria in an operating room; right? personally concerned about dust, that you had some A. But as I said earlier, we don't want it, but 21 21 22 experience with dust gathering on the motherboard. 22 it's -- achieving that total eradication is not

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possible.

Q. I understand that, doctor. But the

question, I guess, is not about whether or not it's

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-- a --

Why are you concerned about dust?

A. It's -- The -- The dust is -- The dust is a

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possible to achieve the total eradication of bacteria, 1 but rather, that you don't want to have bacteria in an 2 3 operating room because it can cause an infection; 4 right? 5

- A. You want to minimize the -- the amount of bacteria.
- Q. All right. And you'd agree if it was possible you'd prefer to have zero bacteria in an operating room; right?
- 10 A. That's a hypothetical that I know is not 11 achievable.
- Q. Right. But that would be ideal; correct? 12
- 13 A. As an engineer I must say it's -- it's -it's a -- it's an untenable proposition. 14
  - Q. It's an untenable --
- A. Yeah. 16

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- 17 O. -- ideal?
- A. Yeah. 18
- 19 Q. All right. So getting back to your -- your 20 interest with dust on motherboards in an operating room, why do you care about that? 21
  - A. I thought I already answered that.
- Q. All right. Because you want to minimize the 23 24 dust that might be present in an operating room; is 25 that fair?

Q. -- and the reason you care about whether it's cleaned on a regular basis is because you want to minimize dust in the operating room. Is that correct?

Page 20

- A. That's -- That's not my responsibility, just to be clear, about -- you know, I -- like afterwards I didn't tell the biomedical engineer, from now on you need to do that. I was just trying to understand, this is a -- a -- I was just trying to -- I was trying to understand the process.
- Q. Okay. And I think we're missing each other a little bit, because you're answering questions that I didn't ask.
- A. Okay.
- Q. So I want to know why...

You said that you're concerned about dust on a motherboard and that -- that you want to minimize the dust in an operating room; is that correct?

18 I appreciate that you may not be the person 19 doing the cleaning, --

- A. Right.
- 21 Q. -- but -- but you were personally concerned 22 about dust on a motherboard; is that correct?
  - A. That is correct, and -- and the dust also can interfere with the operation of the equipment in the sense of if it builds up enough it can interfere

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Page 21

- A. It's -- It's to keep what you can keep 2 clean, clean.
  - Q. Right.

And one of the reasons that you want to minimize dust on the motherboard is to minimize potential bacteria; right?

- A. Can you repeat the question, please?
- Q. Sure.

One of the reasons you would want to minimize dust on the motherboard is to minimize potential bacteria in an operating room; correct?

- A. Well it's -- it's not a given that the dust has bacteria, I want to make clear, that it's a possibility. So the idea is, if it's dusty, let's clean it, because it's an overlooked part.
- Q. Okay. And that's -- you want to minimize those dust particles as much as possible; is that fair?
- A. I was actually looking at whether this was something that the biomedical engineers do on a regular basis, because that's what -- yeah. I wanted to see whether they did it on a regular basis.
- Q. Okay. So you want to see if they -- if they clean it on a regular basis, --
  - A. Umm-hmm.

1 with the cooling, et cetera.

- 2 Q. Okay. So there are a multitude of reasons 3 that you don't -- you want to minimize dust in an operating room. Is that fair? 4
  - A. I was looking to minimize the -- in this particular conversation, the dust on the motherboard.
  - Q. Okay. And one of those concerns may be to ensure that the machine itself works properly; is that correct?
- 10 A. That the -- the motherboard and the electronics can continue to work. 11
  - O. Yes.
- 13 So the answer is "yes"?
- 14
- 15 Q. Okay. And another reason is because dust --16 dust can contain bacteria; is that fair? 17
  - A. It can, but sometimes it doesn't.
  - Q. Okay. Let's go back to the deposition that you had taken a few years ago. I think you said it involved a bad outcome for a patient? Did it also in

-- or was that bad outcome caused by a product of some 21 22

- kind? 23
  - A. That was what was alleged.
- 24 Q. All right. And what wa -- what was the bad

25 outcome, if you know?

Page 22 Page 24 A. I do. I'm trying -- I'm thinking, because I 1 Q. Have you had any other cases with Ms. Cohen 1 2 besides the -- this burn case you mentioned? 2 want to make sure this is not still protected. 3 Q. Is this the case about the burns? 3 A. Well there was the case with Mr. Walton. 4 A. Yes. 4 5 5 Q. Okay. And do you know what ultimately And do you understand Mr. Walton's case is 6 happened to that case? 6 part of the case I work on and Mr. Assaad works on? A. Yes, I do. 7 A. I -- I don't have information either way. I 7 8 Q. All right. What happened? 8 -- I would be assuming. 9 A. The manufacturer was found not guilty. 9 Q. Okay. So Mr. Walton's case, is that the only other case you worked with Ms. Cohen on besides Q. Okay. Was there a trial? 10 10 A. Yes. this fire -- or pardon me, the burn case? 11 11 Q. And did you go testify at trial? 12 A. Yes. 12 13 A. Yes. 13 Q. Okay. And, let's see, I think Mr. Walton's 14 case was first filed in 2013, and Ms. Cohen was Q. All right. And there was a jury there? 14 involved with the case at least through 2015. Is it a 15 A. Yes. 15 Q. And the jury determined the manufacturer was fair assumption that if Evan Holden is the person who 16 16 not responsible for the injuries? 17 approached you about serving as an expert in the Bair 17 A. I don't know who made the determination. Hugger litigation, it must have happened certainly no 18 18 later than 2015? 19 Q. Okay. But in any event, your -- your 19 20 understanding is that there was a not guilty verdict; 20 A. I'll go by what you say. is that right? 21 Q. Okay. 21 A. I don't have those dates. 22 22 A. That's --23 I don't have personal knowledge of it. 23 Q. Well Ms. -- Ms. Lewis and her law firm I 24 That's what counsel told me. 24 believe took over the matter sometime in 2015, so if Q. Okay. About how long were you on the 25 25 -- if Ms. Cohen and Mr. Holden retained you, it would Page 23 Page 25 witness stand for that trial? have been prior to -- prior to Ms. Lewis becoming 1 1 A. It's a long time ago, and I'm guessing. I 2 involved in this case; is that fair? 2 3 would say two to three hours. 3 A. If -- If I assume that what you're telling 4 Q. Do you remember the name of the lawyers who 4 me is correct, then it's logical, --5 retained you? 5 Q. Okay. 6 A. -- ves. 6 A. Yes. 7 Q. And who are they? 7 Q. Well did you -- did you meet with Ms. Lewis 8 A. Lori Cohen. or any of the other attorneys from her firm and with 9 Q. Oh, from Greenberg Traurig. 9 Ms. Cohen at the same time? 10 And did she first approach you with respect 10 A. Oh, no. to this Bair Hugger litigation as well? Q. Okay. Now they -- 3M and Arizant Healthcare 11 11 12 A. Evan Holden did. 12 have designated you as an expert witness in this case. Q. Okay. And when did -- when were you first 13 13 You -- As we go through the questions today I want to approached regarding the Bair Hugger case? make sure that you know that you're offering expert 14 14 A. I don't remember. opinion. You understand that? 15 15 Q. Was it shortly after that trial? 16 16 A. Yes. A. I -- I don't remember. 17 17 Q. Okay. And so we're not asking for you to guess as I ask you questions today, we want just those 18 Q. Is there a retention agreement of any kind; 18 did you sign a contract? opinions that you hold to a reasonable degree of 19 19 20 A. I don't remember either. 20 engineering certainty. Is that okay? Q. Okay. Do you have any other cases with Ms. 21 21 A. Yes. 22 22 Cohen? Q. All right. And as an expert witness you are expected to be objective. You understand that? 23 A. Currently? 23 24 Q. Yes, currently. 24 A. Yes. A. No. 25 25 Q. Okay. And you are not -- you are not

Page 26 Page 28 expected to be an advocate. Do you understand that? have the -- the exhibit copy and I guess one other 1 1 2 A. Yes. 2 copy that's been provided today. 3 Q. And we started the deposition today with an 3 (Handing Exhibit 1 to the witness.) oath, so you understand that you are providing answers 4 A. Yes, that's what it says. 5 today under penalty of perjury. You understand that? 5 Q. And are these a complete and accurate 6 A. Yes. 6 reflection of the work, or the time you've spent 7 Q. What did you do to prepare for your 7 working on this matter? 8 deposition today? 8 A. It's not complete because I have not put in 9 A. I reviewed some of the materials, I reviewed 9 the time today and yesterday, I believe. my report. 10 Q. Okay. So other than the time you spent 10 yesterday and today, this is a complete, accurate 11 Q. Did you bring anything with you today? 11 A. No. summary of the time you've spent on this matter? 12 12 A. It is possible I left out some other stuff Q. Why not? 13 13 A. Oh, you mean -- I'm sorry. 14 because I -- like if you -- if you look at the last 14 You said did you bring anything. I mean, I one, I just made some notes on a piece of paper that 15 15 left all my luggage upstairs. was available. Publix is a big supermarket here. 16 16 17 Q. Okay. 17 O. Looks like a grocery list. A. I'm sorry. I -- I brought the stuff in 18 A. Yes. 18 Q. Okay. front of me, yeah. 19 19 20 Q. Okay. And what do you have in front of you 20 A. Yeah. So it may be that there are some 21 21 others, but this is the bulk of it. right now. A. It's just some studies, my -- my -- my --22 O. All right. And then that last page, it 22 not even my -- my -- what do you call it? The thing looks like it's dated 8/9. Is that just earlier this 23 23 24 that was --24 week? 25 A. Yes. 25 Q. The timeline --Page 27 Page 29 1 A. Yeah. Q. Okay. Have you received payment in 1 2 Q. -- that you put together reflecting the time 2 connection with your -- your work on this matter? you worked on this case? 3 A. No. 4 A. Umm-hmm. 4 Q. You have received no payment for the time O. And I will -- we have marked already for 5 5 that you've spent on this case? this exhibit -- or pardon me, for this deposition, 6 6 A. No. Lampotang Exhibit 1, which is a six-page document that 7 7 Q. Okay. Why is that? was provided to us this morning. 8 8 A. Because I didn't -- I did not invoice. 9 Are these -- Do these notes reflect the time 9 Q. You did not send an invoice. Is it your that you have worked on this matter? plan to send an invoice? 10 10 11 A. Yes. A. Eventually. 11 12 Q. All right. And the first entry on page 1 is 12 Q. Okay. And do you have an agreement that you dated 5/2/2016, that's May 2nd of this year. Is that 13 13 will just get paid at some future date? the first time you worked on this matter? A. I don't -- I don't know that I have an 14 14 A. We are 2017 now. 15 15 agreement. I just trust that when I send my bill it 16 Q. Right. 16 will get paid.

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Okay. So 5/2 of 2016. Is that the first time you worked on this matter?

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A. I would assume so, that's what -- if that's 19 20 what it says, yes.

- Q. Okay. And that was a meeting with Corey 21 Gordon; is that right? 22
- A. I believe so. I'm not looking at what you 23 24 are reading so, I believe so.
- Q. All right. Yeah. Unfortunately, we only 25

A. There is really no specific reason except it takes -- it takes time. I don't have somebody helping me to, you know, transcribe all this, add it up, and, so. O. When --Is the work that you're doing and the payment that you will receive, is that personal to you

Q. All right. Is there a reason that you're

waiting to send an invoice?

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or will that go to the University? 1

- A. That would be personal to me. But I have 2 not decided that actually, so I would -- I would take that back. I -- First of all, I have not receive -- I have not billed, so therefore I have not received any 6 funds. And, you know, there is a project I am doing 7 right now that is actually very meaningful to me and 8 the University, and I am thinking about possibly
- donating part of the proceeds to help with that 10 project. 11
  - Q. All right. What is that project?
  - A. That project is to equip medical students and our anesthesia residents with pocket-size ultrasound scanners.
    - Q. Ultrasound scanners?
- A. Umm-hmm. 16

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- 17 Q. And why would you do that?
- A. Because the technology whose potential --18 that technology is there, the price point has made it 19 20 affordable, but it's not being adopted. And I believe 21 the technology should be more adopted, and one way to 22 do that is to let people use it and appreciate what it 23 can do.
  - Q. All right. And you've -- you've had experience, it sounds like personally, technology,

1 A. -- image?

- O. Yes.
- A. It produces an ultrasound image. Instead of wheeling a big thing the size of this camera, but bigger, it's in your pocket.

Page 32

Page 33

- Q. All right.
- 7 A. So it's like you were talking about the 8 phone, how the phone has changed.
  - Q. So it's essentially a pocket-sized ultrasound machine?
    - A. Correct.
- 12 Q. Okay. And that's something that you expect 13 will help in the care and treatment of patients; is that fair? 14
  - A. As a scientist I cannot say that. I can say it will hopefully -- That's what I was trying to do is put it out there, make it accessible, see whether we -- and then we would run a study and look, okay, you've had this now, it's at your fingertips, has it changed what you've done, has it made your patient care better? And, more importantly, has it made your patient outcomes better.
- 23 Q. Right. Because that's very important; 24 correct?
- 25 A. Yeah. Patient outcomes is important.

Page 31

there are advances from time to time; is that right?

- A. Yes.
- Q. We all carry around these phones now that are more powerful than most of the computers we probably all went to school with; is that right?
  - A. Yes.
- Q. And adopting technology for the improved care of patients, is that something that you care about?
- A. It's not about adopting technology. I --That -- I think that would mischaracterize it. This is a particular piece of technology that I think is -is underused. There are other pieces of technology that I have actually voted against, so.
- Q. Okay. Why -- Why is this piece of technology, the ultrasound scanner, is that what it is?
  - A. Yes.
  - Q. Why do you think it's underused?
- 20 A. I think it's underused because of people not appreciating how having it all the time will change 21 how they practice. 22
- 23 Q. How is it used?
- 24 A. Are you familiar with an ultrasound --
  - Q. With an ultrasound? Yes.

Q. Right. In fact you'd agree that patient 1 2 safety is paramount; correct?

A. Patient safety is important, but it has also to be something that is efficacious. So just safety by itself, without effectiveness, is -- there are -there are multiple elements involved is what I want to say. So yes, safety is what -- is what we strive for and we -- but the -- the efficacy and effectiveness is equally important.

Q. Right.

But patient safety and out -- and good outcomes are the number one goal in a hospital. Does that seem fair?

- A. The --
- Q. Is there something that's more important than patient safety to a hospital, if you know?
- A. Well I'm not -- I'm not a -- I'm not a hospital administrator, so I will start by that, but I do -- I work in a hospital environment. And safety is important, but there are also other considerations.
  - Q. Yes, there are.

22 But is there a consideration that's more 23 important than patient safety that you're aware of?

- 24 A. The unit has to work, like -- like I said.
- 25 So we won't buy something if it's extremely safe but

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the data shows it doesn't do what it's supposed to do. 1

- Q. Okay. But my question was: Is there something more important than patient safety that you're aware of at a hospital?
- A. And I thought I already answered that. Yes, 5 6 it is important.
  - Q. Okay. Thank you.
  - A. And -- No, but what I was trying to say, it is important, but there is also other factors.
  - Q. Right. And we can talk about various procedures and devices and drugs and all sorts of things where there's a risk-benefit analysis, I understand that, but I think that we can agree that patient safety is the most paramount concern.
  - A. Okay. I guess that was not a question, so I -- I won't answer.
- 17 O. Did you rece --

Do you recall receiving a subpoena in this 18 19 case?

20 A. Yes.

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- 21 (Lampotang Exhibit 2 marked for identification.) 22
- 23 BY MS. ZIMMERMAN:
  - Q. Does this look familiar to you, doctor?
  - A. (Witness reviewing exhibit.) [Clearing

- Page 34 Page 36 O. All right. And starting on page 4 there is
  - a list of "DOCUMENTS TO BE PRODUCED." Do you see
  - 3 that?
    - A. Yes.
  - 5 Q. And the first item on this list asks for
  - 6 "All documents reviewed by the deponent in
  - 7 anticipation of or in preparation for this
  - 8 deposition." Did you see that?
    - A. Correct.
  - 10 Q. Did you identify any documents that are responsive to that request? 11
    - A. What was your question again? Sorry.
  - Q. So this subpoena was provided to you by 13
  - 14 counsel: --
  - 15 A. Umm-hmm.
  - 16 Q. -- correct?
  - 17 A. Yes.
  - 18 Q. And you -- I trust they explained that you
  - needed to collect any documents --19
  - A. Umm-hmm? 20
  - 21 Q. -- that might respond to any of these items
  - listed on pages 4 and 5 of the subpoena. 22
  - 23 A. Right.
    - Q. Did you --
  - 25 Did you do a search for documents?

Page 35

- A. It says "for this deposition"? 1
  - 2 Q. Yes.
  - 3 A. So at the time I was -- I would -- I had not 4 prepared any -- I had not -- I was not preparing for 5 the deposition. 6
    - Q. All right. And the -- any documents that you reviewed in preparation for the deposition since that time, does that include just the documents that you brought with you today?
      - A. Yes.
  - Q. All right. And we'll mark those after we 11 12 get through this.

The second request is for all correspondence between yourself, that's the deponent, and any non-lawyers, including but not limited to notes, investigations, test results, raw data, experiments, demonstrations, et cetera, created in the course of the deponent's investigation of this case.

Do you have any documents responsive to that second request?

- A. Yes.
- Q. And did you provide them to counsel?
- 23 A. Yes.
  - Q. All right. What kind of documents are
- 25 those?

throat.] Excuse me. Yes. Yes.

- 2 Q. And this was provided to you by counsel, I 3 trust?
- 4 A. Yes.
  - Q. And you see then that the subpoena required you to produce documents by June 21st of this year; is that right?
    - A. Can you point me to it, please?
- 9 Q. Well so the first page says it's a subpoena to produce documents, information or objects, and then 10 10 it has your name right underneath that. Do you see 11 12 that part?
  - A. Yes.
  - Q. All right. And in the middle of the page it says you are commanded to produce, at the date, time and place set forth below, the following documents, electronically stored information, et cetera, and then it shows a date and time, June 21st of 2017 at 10 a.m. Do you see that?
  - A. Yes.
- Q. Okay. And then the front page here refers 21 you to Exhibit A, which is at the back half of this 22 23 subpoena.
  - You've seen this document before; correct?
- 25 A. Yes.

Page 37

	Page 38		Page 40
1	A. It's an email.	1	that were provided to you by defendants' counsel on
2	Q. And who is it with?	2	which you have made any notations, highlights, or
3	A. Who is the email with?	3	underlines.
4	Q. Yes.	4	Do you have any documents responsive to
5	A. You mean who I sent the email to?	5	number 4?
6	Q. Yes.	6	A. No.
7	A. Okay. It was to Craig Bakuzonis.	7	Q. "No"?
8	Q. Can you spell that?	8	Documents were provided to you by counsel, I
9	A. B-A-K-U-Z-O-N-I-S.	9	trust?
10	Q. And what was it about?	10	A. I'm sorry?
11	A. It was about whether equipment is opened on	11	Q. Did you pro
12	a routine basis to clean inside.	12	I trust that counsel did provide you with
13	Q. All right. And is he the is he at the	13	documents in this case; correct?  A. Yes.
14 15	University of Florida?	14 15	
16	A. He is the head of our clinical engineering at Shands.		Q. All right. And you just never made
17	Q. Okay. And was it a single email?	16 17	notations on those; is that your testimony?  A. That's correct.
18	A. Yes.	18	Q. Okay. Number 5 asks for any and all
19	Q. Did he respond to your email?	19	essentially exhibits that you might use at trial.
20	A. No.	20	I assume you haven't prepared anything like
21	Q. Do you know why not?	21	that at this time.
22	A. He's busy.	22	A. That is correct.
23	I don't know, so. The answer to your	23	Q. And number 6 and 6 asks for any books,
24	question actually is "I don't know."	24	treatises and articles authored or coauthored by you.
25	Q. Okay.	25	Is the curriculum vitae that you provided
	Page 39		Page 41
1	Page 39  A. He didn't reply.	1	Page 41 in with your report correct and accurate?
2		1 2	
	A. He didn't reply.		in with your report correct and accurate?  A. There may be one or two latest papers missing, but yes.
2 3 4	<ul><li>A. He didn't reply.</li><li>Q. So</li><li>A. I assume he was busy.</li><li>Q. [Coughing.] Excuse me.</li></ul>	2 3 4	<ul><li>in with your report correct and accurate?</li><li>A. There may be one or two latest papers missing, but yes.</li><li>Q. All right. And we'll look at your CV in a</li></ul>
2 3	<ul> <li>A. He didn't reply.</li> <li>Q. So</li> <li>A. I assume he was busy.</li> <li>Q. [Coughing.] Excuse me.</li> <li>So the this single email provided to Mr.</li> </ul>	2 3 4 5	<ul> <li>in with your report correct and accurate?</li> <li>A. There may be one or two latest papers missing, but yes.</li> <li>Q. All right. And we'll look at your CV in a little while here.</li> </ul>
2 3 4 5 6	<ul> <li>A. He didn't reply.</li> <li>Q. So</li> <li>A. I assume he was busy.</li> <li>Q. [Coughing.] Excuse me.</li> <li>So the this single email provided to Mr.</li> <li>Bakuzonis, is that the only document that you</li> </ul>	2 3 4	<ul> <li>in with your report correct and accurate?</li> <li>A. There may be one or two latest papers missing, but yes.</li> <li>Q. All right. And we'll look at your CV in a little while here.</li> <li>And you said that there's no engagement</li> </ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	<ul> <li>A. He didn't reply.</li> <li>Q. So</li> <li>A. I assume he was busy.</li> <li>Q. [Coughing.] Excuse me.</li> <li>So the this single email provided to Mr.</li> <li>Bakuzonis, is that the only document that you identified that's responsive to number 2?</li> <li>A. Yes.</li> <li>Q. Okay. So number 3 asks for copies of all of your notes, whether handwritten or typed, related to your expert work in this matter.</li> <li>Did you search for documents that are responsive to that?</li> <li>A. Yes.</li> <li>Q. And did you provide them to counsel?</li> </ul>	2 3 4 5 6 7 8 9 10 11 12 13 14 15	in with your report correct and accurate?  A. There may be one or two latest papers missing, but yes.  Q. All right. And we'll look at your CV in a little while here.  And you said that there's no engagement agreement, number 9, there's no contract between you and the attorneys for 3M?  A. I think I said I don't remember, but. I think there is not, but I don't remember.  Q. Okay. In any event, you looked once you got this subpoena you looked in your files to see if you had documents that were responsive, and you didn't find one?  A. Yeah. I I didn't I didn't see an
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. He didn't reply. Q. So A. I assume he was busy. Q. [Coughing.] Excuse me. So the this single email provided to Mr. Bakuzonis, is that the only document that you identified that's responsive to number 2? A. Yes. Q. Okay. So number 3 asks for copies of all of your notes, whether handwritten or typed, related to your expert work in this matter. Did you search for documents that are responsive to that? A. Yes. Q. And did you provide them to counsel? A. Yeah, I don't make notes, so. Q. You don't make any notes? A. Well I gave the the I didn't realize these [Exhibit 1] were considered notes, so I but no, I don't make notes. Q. So this this document at Exhibit 1 is the sum total of the notes that you've made in this	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	in with your report correct and accurate?  A. There may be one or two latest papers missing, but yes.  Q. All right. And we'll look at your CV in a little while here.  And you said that there's no engagement agreement, number 9, there's no contract between you and the attorneys for 3M?  A. I think I said I don't remember, but. I think there is not, but I don't remember.  Q. Okay. In any event, you looked once you got this subpoena you looked in your files to see if you had documents that were responsive, and you didn't find one?  A. Yeah. I I didn't I didn't see an engagement agreement, but I I Yeah, I don't recall seeing one.  Q. Let me ask you this. Do you Do you have a box or a file drawer in your office that has all of your Bair Hugger documents and files?
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Q. email? 1 2 A. Yeah. 3 Q. Okay. Dropbox, something like that? A. Yeah. Umm-hmm. 4 5 Q. All right. And do you still have the 6 electronic files that were provided to you by counsel? 7 A. I think most of them, yes. 8 Q. All right. Did you look on your electronic 9 folders to see if there was a retention agreement with 10 counsel? 11 A. I don't recall. 12 Q. Okay. A. I don't recall where I looked. 13 14 Q. All right. And same for number 10. I mean, this is a -- this document, Exhibit 1, is the complete 15 itemized list of time, charges and expenses that --16 17 that you have so far in this case; is that right? A. With the clarification I said earlier that 18 some of the times --19 20 Q. Yeah, yeah. 21 A. -- may be missing, but yes. O. Fair enough. Fair enough. 22 All right. So -- And I assume with respect 23 24 to number 11, you were asked for all documents or other materials you intend to show the jury in this 25 Page 43 case. You haven't decided on that yet right now; is 2 that fair? 3 A. That is correct. 4 Q. All right. The correspondence file, do you 5 have correspondence with anyone other than the lawyers who represent 3M? Recognizing you mentioned the one 6 email to Mr. Bakuzonis. 7 8 A. Apart from the email to Mr. Bakuzonis, no. 9 Q. All right. Have you --Have you corresponded in any way with anyone 10 else about this case, other than the lawyers? 11 12 A. No. 13 Q. All right. You haven't --You haven't written to anyone at the 14 University of Florida to discuss your work on this? 15 A. Oh, I'm sorry. Yes. I have to get what's 16 called outside activity waiver. 17 18 Q. Okay. A. So that's a standard procedure. So I have 19 20 to say who retained me, what is the case. Q. All right. 21 A. So yes. 22 23 Q. And you did that in this case? 24 A. Yes. 25 Q. All right. And have you provided a copy of

Page 42 Page 44 that outside activity waiver to counsel? 1 A. I don't remember. 2 3 Q. Okay. In any event, you haven't had other communication with the University of Florida about 5 your work on this? Once they approved it, you haven't talked about your work on this case? 6 A. That's correct. 7 8 Q. Okay. You haven't communicated with the 9 CDC, for example. 10 A. No. 11 Q. Okay. And you haven't communicated in any 12 way with the FDA. 13 A. No. 14 Q. Okay. Have you communicated with any employees at 3M? 15 A. No. 16 17 Q. And have you been in any communication with 18 employees at Arizant? A. No. 19 20 Q. All right. What about Augustine Medical? 21 A. Is this, like, an open timeframe, or is this 22 -- What timeframe are you --23 Q. Well the subpoena I think sets a timeframe 24 of since 1995. 25 A. Oh, 1995? Then it's possible.

ge 43 Page 45

1 Q. All right. Possible with respect to 2 Augustine, or possible that you need to clarify your

Augustine, or possible that you need to clarify your 3 --

4 A. Augustine.

Q. Okay. Do you know Dr. Augustine?

6 A. I have met him.

7 Q. Okay. When?

8 A. I don't remember.

9 Q. In the last year?

A. No.

5

10

11 Q. Last five years?

12 A. No. Probably 10, 15, maybe even 20.

Q. Where?

14 A. At the American Society of Anesthesiologists 15 meeting.

Q. Okay. And tell me about that meeting. With Augustine, not the conference.

A. Yeah. He was, I believe, this is again my vague recollection, but I believe he was in his booth and demonstrating most likely a new version of the

21 Bair Hugger, and -- and at the end I think I talked to

22 him briefly.

Q. Do you know what color the Bair Hugger was that he was demonstrating?

A. I don't remember.

12 (Pages 42 to 45)

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Page 46 Q. But in any event, what -- when you had the 1 2 meeting with Dr. Augustine, or when you --3 A. Ran into him --Q. -- yeah, ran into him. 4 A. -- would be more accurate. 5 6 Q. Okay. It's your sense, anyway, that he was still involved with the Bair Hugger at the time; is 7 8 that fair? 9 A. Well I could actually be wrong. Maybe he was -- he was already Arizant, I don't know. 10 Q. Okay. But to the best of your recollection 11 as you sit here today, you think that he was 12 demonstrating the latest version of a Bair Hugger? 13 A. I believe so, but again, that's a long time 14 15 ago. Q. Okay. 16 A. All I can say for sure is that I met him. 17 18 Q. Okay. Have you --Have you spoken with any of the other 19 20 experts in this case? A. For the --21 22 For the defense, or for the plaintiffs?

performed on the Bair Hugger warming system or filter 1 for use with any Bair Hugger warming system, including 2 3 any work in progress. 4

Do you have any such documents?

A. No.

Q. And have you had any communication to or from any other forced-air warming system manufacturer about the potential hazards involved with that type of patient warming?

A. No.

Q. And then finally, number 18, are there any compilations of electronic data or computer files that you have created, including but not limited to pictures, videos, animation, CFD files, that sort of thing. Are there any documents like that?

A. No.

17 Q. Okay.

A. There are some documents that are -- that 18 were already created that I referred to in my expert 19 20 report, yeah.

21 Q. Okay. But nothing that you specifically 22 created; --

23 A. No.

24 Q. -- correct?

25 All right.

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asks for any other documents, photographs or other 1 material that's not really listed on here, 2

Q. I should ask, with respect to number 13, it

specifically listed on here that you rely on for your opinions in this case.

Is there any such document or pictures? You didn't reference anything in your report.

A. I'm sorry?

Q. Sure.

O. Both.

A. No.

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So number 13 asks you to produce "any other documents, photographs or other material not specifically listed above" on this subpoena --

A. Right.

Q. -- that -- "upon which the deponent," you, "rely for your opinions."

Are there any other photographs or other things that you intend to rely upon in support of your opinions?

A. I think what -- what I relied upon is in the report, the references, yeah.

Q. Okay. We'll get to that in just a minute. Number 16, so if you turn the page to page 5, it asks about any study, test, trial, experiment, research and/or data analysis that the deponent has

sponsored, conducted, performed, proposed, attempted, considered, discussed, planned, arranged and/or

1 MS. ZIMMERMAN: And counsel, to the extent 2 that this email to Mr. Bakuzonis was provided by the 3 witness and has not been provided to us --

MS. LEWIS: I can get it to you at the -when I turn on my computer. I got it yesterday.

MS. ZIMMERMAN: Okav.

MS. LEWIS: And I can try to gin up an email to you.

MS. ZIMMERMAN: Well you can gin it up if you want, but the -- the response to this subpoena was due on June 21st.

Q. I understand from your testimony today you 13 did provide one document to counsel that has not been provided to us.

MS. LEWIS: That's what I'm saying I got yesterday. That's what I'm saying, I will email that to you.

MS. ZIMMERMAN: All right.

19 MS. LEWIS: I got it yesterday. 20 MS. ZIMMERMAN: All right.

BY MS. ZIMMERMAN: 21

Q. And when did you provide it to counsel?

23 A. Yesterday.

24 Q. All right. Is there a reason that it was 25 not provided at the time that it was -- the due date

Confidential - Subject to Protective Order Page 50 Page 52 for the subpoena, which was June 21st? much when you received it, but you certainly had it by 1 June 13th. Does that seem fair? A. I -- I -- I guess I just forgot about it, 2 2 3 and then yesterday, in going over this, we -- I said, 3 A. Yes. Q. If you're reviewing it on the 13th, you had 4 4 yes, there was. 5 5 to have had it by then? O. Okay. Is there anything else that you 6 discovered yesterday, as you were preparing for the 6 A. Yes. deposition today, that should have been disclosed in 7 Q. And -- And then you also note that you're 8 connection with this subpoena? 8 emailing a reply that same day; is that right? 9 A. The -- The notes. 9 A. Correct. 10 Q. The notes that you also did. All right. 10 O. And I assume that's to Ms. Lewis or one of A. Yeah. 11 11 the other counsel for 3M; is that right? 12 Q. How much time did you spend searching for 12 A. I assume, yes. documents that are responsive to this subpoena? Q. Okay. And -- And that reply included 13 13 A. I don't recall. 14 responsive documents, or it did not? 14 Q. Would it be reflected in your notes in A. I don't recall. 15 15 Exhibit 1? Q. All right. What are the --16 16 17 A. I -- I don't know. I have not reviewed my 17 What does the note say here for 6/20, 18 notes. I don't -- I don't know. 18 "hold"? I can't read that. A. Hold and email. 19 Q. So if your notes on, it looks like the 19 20 second-to-last page of Exhibit 1, show, on June 13th, 20 Q. Hold -- Hold email. What's that mean? 21 "Review subpoena and email reply, 30 minutes," you'd 21 A. I think this -- I can't recall. I -- I 22 assume that that would be accurate? 22 would assume... No. I --23 A. No, not necessarily, because... 23 MS. LEWIS: You don't have to guess if you 24 Where are you looking? 24 would assume, but. 25 Q. The second-to-last page of your notes on 25 Q. Well we submitted a subpoena, and counsel's Page 51 Page 53 Exhibit 1, there's an entry -- there are actually two 1 certainly aware of that, and this -- this is not entries in particular I'm interested in. One says 6/9 provided to us until today, so the best I can do is to 2 of 17, and --3 3 try to understand your notes --4 4 A. Yeah. A. Umm-hmm. 5 Q. -- it says from 12:35 to 1:21, "emails and 5 Q. -- that reflect the work you put in, what 23 minute call," with an arrow, and then it says "DL." 6 6 you reviewed, all that sort of thing, and so we're 7 I assume that's Deborah Lewis? required to do that on the fly today. What can you tell me from -- from these 8 8 A. Yes. 9 Q. Is that right? 9 notes, that you did on June 20th and June 21st of this 10 And then the next entry is 6/13, and it 10 year? Or don't you understand your own notes? A. No, I -- I -- well I can -- I can read it. looks like it shows 3:33 to 3:55, on the second line 11 11 12 says "review subpoena and email reply." 12 It's just, as you can see here, it's very cryptic. So my best guess is the "hold" refers to 13 Is that accurate? 13 14 holding open some dates because, as you see on 6/27 I 14 A. Yeah.

Q. That's what your notes say?

Q. So this would be reflective of when you got 17 18 the subpoena and when you provided a response; is that 19 right? 20

A. I can't tell from that. I don't know when I received it. So what -- if I understood your question correctly, you're saying this would mean I received it

on the 13th, so I don't know that I received it on the 23

24 13th. 25

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Q. Okay, doctor. I don't know that I care so

15 met with Deb Lewis.

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Q. Yeah. I see that you met with her for several hours on the 27th, and it says "Dep Prep." I assume that's deposition prep or preparation.

But what I'm concerned with right now is what was emailed to counsel on June 13th, and what was held on the 20th and 21st?

MS. LEWIS: Objection, form.

A. Okay. Can you repeat the question, please?

O. So your --

These are your notes; right?

Page 54 Page 56 A. Yes. 1 A. -- I cannot remember. 1 2 Q. And -- And it's important that they be Q. Let me ask you this. Are there any facts, 2 accurate because you're going to submit, at some 3 in emails you've received from counsel, that you rely point, an invoice for your time in this matter; upon in offering your expert opinions in this matter? 4 5 5 A. I would -correct? 6 A. Yes. 6 MS. LEWIS: Objection, form. 7 Q. All right. And so you have recorded that on 7 A. -- have to defer to counsel whether I can 8 June 9th that you had emails and a 23-minute call with 8 share that kind of a topic. I thought what I DL, which we've established is Deborah Lewis. A few 9 discussed -- discuss -- sorry -- discussed and discuss days later, on June 13th, your notes show that you 10 with counsel is -- is -- is privileged. 10 reviewed the subpoena, which we've been asking Q. The actual conversation may be, but to the 11 11 questions about for the last 20 minutes, and you extent that there are facts upon which you rely, that 12 12 13 emailed a reply, and that was back on June 13th. 13 is not privileged. You understand that this is a legal document A. Okay. 14 14 that commands you to produce documents at a certain Q. So, you know, facts about the Bair Hugger, 15 15 time and date: correct? or facts that are contained in your expert report 16 16 17 A. Umm-hmm. 17 which we'll be talking about today, if you received facts from counsel that you are relying upon, that's 18 O. And --18 THE REPORTER: Your answer, please? 19 19 not privileged. 20 20 Are there any such facts that you received Q. All right. And you did in fact review that; 21 from counsel that you rely upon in attempting to offer 21 expert opinions in this case? 22 correct? 22 23 23 A. No, I don't think so. A. Yes. 24 Q. And you searched for documents that would be 24 Q. Okay. At any rate, you reviewed a subpoena responsive to this subpoena; correct? 25 and did some search for documents responsive to the 25 Page 55 Page 57 subpoena back in June; is that fair? A. Yes. 1 1 Q. All right. And you emailed a reply on June 2 2 A. Yes. 3 Q. Okay. And you're not sure, as you sit here 3 13th; is that right? 4 A. Yes. 4 right now, when -- when it was you sent the email that 5 Q. Okay. You -- You held an email, or your 5 you sent to Mr. Bakuzonis to counsel; is that fair? best understanding of your notes from June 20th and 6 6 MS. LEWIS: No. He said yesterday. 21st say "hold email"; is that right? 7 7 A. Yeah, I -- I thought I told you I sent it 8 A. No. It says "hold + email." 8 yesterday. Q. "Hold plus email." What does that mean? 9 9 Q. Okay. So you didn't -- you didn't send A. It's -- It's holding dates open, -anything in June. 10 10 A. That is correct. 11 O. Okay. 11 12 A. -- I believe. 12 Q. All right. Q. And is that to schedule your deposition, or 13 13 A. You mean I didn't send the email to schedule preparation, or? 14 Bakuzonis, right, in June? 14 15 A. I -- I don't remember. 15 Q. What is the date of the Bakuzonis email? A. I think it was in May, but I --16 Q. But as you sit here today you either don't 16 know or don't recall whether this was about the 17 O. Of 2017? 17 A. Yes. 18 subpoena; correct? 18 A. Well this is -- as we said, this is for Q. Okay. We're going to get to the report here 19 19 20 billing purposes. This just reflects the time I put 20 in just a few minutes, but you understand that one of

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in the case, and.

Q. Okay.

So it could either have been holding dates

open -- I'm -- No. I think it's about holding dates

open, but dates for what, I cannot --

the purposes of the deposition today is so that we can

understand what opinions you intend to offer to the

Q. Okay. And you understand that we are

Court in this case; correct?

A. Okav.

Page 58 Page 60 interested in the methodologies on how you reached with this case; have you? 1 your opinions? 2 2 A. No, I have not. 3 A. Yes. 3 Q. Okay. In fact you'd agree that you haven't Q. Okay. And -- And that's really so that we 4 4 personally done any original testing with respect to 5 the Bair Hugger matter at all; is that correct? can -- we can test and understand whether your 6 methodologies and conclusions are reliable, okay? Do 6 A. Correct. 7 you understand that? 7 Q. So what your -- your report is really kind 8 8 of a recitation of critiques that you have with A. Yes. 9 Q. Whether they're reasonable and supportable? 9 respect to various peer-reviewed studies and expert 10 A. Yes. 10 reports offered by the plaintiffs in this matter; is 11 Q. Now you didn't personally do any -- any 11 that fair? testing in this case; did you? A. Can you repeat the question, please? 12 12 A. No. 13 13 O. Sure. 14 Q. So you didn't do any biological testing in 14 I said: Your report is really a recitation connection with your work on this case; correct? of critiques that you have with respect to various 15 15 peer-reviewed studies and also expert reports offered 16 16 17 Q. And you didn't do any filtration testing in 17 by the plaintiffs in this matter; is that fair? connection with your work on this Bair Hugger case; A. I think it also includes what I've done, my 18 18 background, my qualifications, the expert report. have you? 19 19 20 A. No. 20 Q. Yes. 21 Q. All right. And you didn't do any particle 21 A. So it's -- there's a little bit more than what you described. 22 counting in connection with your work on this matter; 22 have you? 23 Q. Okay. And your expert report, there's a 23 24 A. No. 24 report, there's your -- your curriculum vitae, and 25 25 there's a lists of materials considered; is that Q. All right. And you haven't done any Page 59 Page 61 compu -- computational fluid dynamics analysis in this correct? 1 matter; have you? 2 2 A. Yes. 3 3 A. Can you clarify what you mean by Q. Three separate documents? Okay. "computational fluid dynamics analysis"? 4 4 And I guess the question I was getting at is 5 Q. Do you know what computational fluid 5 -- is really this: You didn't do any original testing yourself in offering the opinions that you offered in 6 dynamics is? 6 7 A. Yes, I do. your report; correct? 7 Q. All right. 8 8 A. I did not do original testing. 9 A. I have actually used it. 9 Q. Okay. Now with respect to the report --10 Q. Yes, you have, from time to time. 10 (Discussion off the stenographic record.) Have you been asked to use computational (Lampotang Exhibit 3 marked for 11 11 12 fluid dynamics in this matter? 12 identification.) A. No. 13 13 (Discussion off the stenographic 14 14 Q. Okay. And so you --15 Pardon me. 15 (Recess taken from 9:52 to 10:00 a.m.) 16 A. Yeah, you -- because I -- I was wondering 16 BY MS. ZIMMERMAN: what you meant by "analysis." I did -- I did look at Q. Doctor, just before we took a break we 17 17 18 the Elghobashi report, which is a CFD analysis. 18 marked a copy of the report that you prepared and Q. Okay. Right. submitted in connection with this litigation. Is this 19 19 20 A. As well as the Memarzadeh. 20 a -- a complete and accurate copy of the report that you provided? Q. Okay. So you looked at Dr. Elghobashi's 21 21 report and Dr. Memarzadeh's re -- article? 22 A. I believe so. 22 23 A. Yes, article. 23 O. Okay. 24 Q. But you haven't personally performed a 24 A. I mean, you gave me the copy, so... computational fluid dynamics analysis in connection 25 Q. All right. And I'll represent to you it's

Page 62 Page 64 what we were provided by counsel. wanted to make with respect to your report? 1 1 Did you review this document in preparation 2 2 A. Yes. for your deposition today? 3 Q. And what's that? 4 A. Yes. A. I -- In reading the table, I believe for 4 5 5 Avidan, I incorrectly said that two types of bacteria Q. All right. And are there any corrections or 6 changes that you wish to make at this time? 6 were isolated from the -- or were obtained from the 7 A. I don't know that it's a correction, but it 7 WarmTouch. 8 was ambiguous, so the part about the -- can't remember 8 Q. Okay. now, let me see where it is. The SCIP measure. 9 A. And it was really only one. 10 Q. And do you know where that part of your 10 Q. Yep. report is that you'd like to change? 11 A. So that is -- it's not -- it's 11 A. I'm looking for it. 12 not in force any more. 12 Q. Is that the bottom of page 11? 13 Q. You under -- And so we are -- you're 13 referring to the top --14 A. Correct. 14 It's towards the top of page 4; is that 15 Q. All right. And do you want to mark on your 15 right? -- on the exhibit the part that needs to be changed? 16 16 17 A. Yes. 17 A. Yeah. I believe -- I don't have Avidan in Q. Surgical Care Improvement Project, and you 18 front of me, but I believe, from memory, that the 18 mentioned SCIP 10? Aspergillus Fumigatus was not there. 19 19 20 A. Yes. 20 Q. So you want to remove that? Q. And you understand that the SCIP 10 protocol 21 A. Yeah. I crossed out, --21 is no longer in place? 22 22 O. Okav. 23 23 A. Correct. A. -- in my copy, "Aspergillus Fumigatus." 24 Q. All right. And so that's the correction 24 Q. Okay. Are there any other changes that you that you wish to make? 25 wish to make to your report? 25 Page 65 Page 63 A. Nothing that comes to mind right now. A. That's one. 1 1 Q. All right. And so with respect to the SCIP 2 Q. Okay. And -- And you spent yesterday 2 3 reviewing your report and otherwise preparing for the 10, do you just -- what -- what precisely is the 4 correction that you intend to make there, that --4 deposition today? 5 A. Well that's --5 A. Yes. 6 6 Q. -- just essentially remove that? Q. Okay. And you identified a couple of errors A. It's not really a correction. I just want 7 7 or changes that you wanted to make and you have to clarify the way it's written it's a bit ambiguous. 8 notified me of those; correct? 9 It may be misconstrued as saying it is in force, --9 A. I've notified who? 10 Q. Right. 10 Q. Notified me, just now, --A. -- and --11 11 12 Q. And -- And that's not the case any more; 12 Q. -- of the errors or changes you'd like to 13 correct? All right. 13 make. THE REPORTER: I'm sorry. I did not get an 14 14 15 15 answer. Q. And you do that because it's important to be Q. The SCIP 10 protocol has been retracted; is 16 accurate: correct? 16 17 17 that fair? A. Yes. 18 18 Q. All right. And so you've reviewed your A. Oh, I'm sorry. report and you stand by the report with those 19 I didn't answer. 19 20 Q. I think the court reporter just wanted a 20 modifications we've just discussed; correct? 21 confirmation of that. 21 A. Yes. A. Okay. Yes. 22 Q. Okay. I'm going to ask you to turn to the 22 23 Q. The SCIP 10 has been retracted, okay. 23 end of your report, pages 16 and 17. And is this a --24 Good. I think we have a good record there. a complete list of references upon which you rely with 24 25 All right. Is there another change that you respect to the opinions you offer in your report? 25

Page 66 Page 68 A. "This" being pages 16 and 17? reference. I was writing this as a -- as an academic. 1 1 2 Q. All right. And when you say you were 2 O. Yes. 3 And so it looks like they're end notes 3 writing "this" as an academic, you're talking about beginning at "i" and going through Roman numeral 4 Exhibit 2 [sic], your --4 "xvi"; is that correct? 5 5 A. Where I put --6 A. There was this other list. 6 Q. -- report; correct? Q. And we'll get to that in just a minute. 7 A. -- the references, yes. 7 8 So this is -- these are the citations upon 8 Q. Okay. And you put references down when you are citing to someone else who agrees with the 9 which you rely as supportive of the opinions you offer 9 in your report; is that correct? proposition that you are stating in your report; is 10 10 A. Yes. 11 11 that fair? Q. And this is complete? 12 A. No. Who -- I don't know whether they agree, 12 but what they found, the evide -- the facts are 13 A. Yes. 13 14 relevant to the case. Q. All right. And then, in addition --14 MS. ZIMMERMAN: I'll mark -- Is this Q. Okay. And perhaps it's really that you 15 15 agree with what they said or you're looking at their 16 Exhibit 4? 16 17 THE REPORTER: Correct. 17 findings; is that fair? (Lampotang Exhibit 4 marked for 18 A. I wouldn't say that I agree. It would be 18 identification.) really that the -- the facts are valid. 19 19 20 BY MS. ZIMMERMAN: 20 Q. Okay. And that's with respect to those Q. And Exhibit 4 is -- was also provided to us 21 documents in the -- at the end note of your academic 21 22 report; is that right? 22 in connection with your report. A. When --23 A. Umm-hmm. 23 24 Q. I believe that this is Exhibit B, and these 24 What you call "end notes," is this -- this are the other materials you considered but perhaps did 25 is what I call "references," so. 25 Page 67 Page 69 not rely upon; is that correct? Q. Okay. That's fine. 1 1 A. These are materials I considered but didn't 2 "References." And that's -- I think we use 2 3 3 include in the references. the same term. 4 Q. Because they're materials that you 4 A. Okay. 5 considered, but they're not specifically materials 5 Q. The references are things that you rely upon that you're relying upon in offering your opinion. Is in connection with your report. 6 6 that accurate? 7 A. I would say I rely on both sets, because I 7 8 didn't understand the difference that you --8 A. I'm not sure I understand the difference. 9 I'm sorry. 9 Q. Okay. So you're also relying upon all of the documents listed on Exhibit 4? Q. So I think from a lawyer's perspective we 10 10 want to know the full universe of -- of information A. I'm really a bit confused. So this is what 11 11 12 that you had available to you that you considered as 12 I reviewed and considered, and -- so I don't know what you were thinking about the problem -the meaning of "rely" means. 13 13 A. Umm-hmm? Q. Okay. Let's start with Exhibit 4. Is that 14 14 15 Q. -- and shaping the opinions that you may 15 -have with respect to the Bair Hugger case. 16 And if you can set the other ones aside so 16 A. Umm-hmm. that we don't get confused as we're looking at things. 17 17 18 Q. And then the materials that you rely upon, I 18 A. Okay. believe those are the end notes to your report, those Q. The court reporter can take some of the 19 19 are materials that you cite as support for the 20 exhibits as we get finished with them, and you can set 20 opinions that you are offering in this matter. your report aside for just a minute. 21 21 22 Let's look at Exhibit 4. 22 Do you see -- Do you understand the 23 difference? 23 A. Okay. 24 A. I'm -- Actually I'm not sure I do. I was 24 Q. Is that a complete list of all the documents looking at this as an academic more, here's the 25 that you were provided in this case?

Page 70 Page 72 1 A. I don't believe so. 1 Q. -- my job, on behalf of 3,000 people, is to 2 2 understand what you considered, what the bas -- what Q. So this list is not accurate. 3 A. Well I -- I -- I really can't tell because 3 opinions you intend to offer at this case, what the basis is of those opinions, and whether or not they I've received a lot --4 4 5 Q. Okay. 5 are reliable, because if they're not reliable they 6 A. -- a lot of material. 6 won't be offered to the Court and they won't be 7 Q. Well let me ask this. Did you prepare this, 7 offered to a jury. 8 or did counsel prepare this for you? 8 So what we need to understand and what I'm 9 A. I was telling counsel what I was reviewing 9 charged with here, is -- is having -- is knowing what and -- and reading as I was going through the report. you considered, what you relied upon, and what you're 10 10 Q. So counsel prepared this list? intending to testify about. 11 11 12 A. They -- They --12 And it sounds to me from your answers to the No. I prepared the list, but for the questions that this list is not complete. So I'm 13 13 interest of time, and I didn't know how it should be asking: Who prepared it and what's missing? 14 14 A. Well I have to defer to counsel. She told formatted, et cetera, I was emailing as I went through 15 15 these other things I'm reading as part of the report, me not to answer. I assume. 16 16 17 as part of preparing the report. 17 MS. LEWIS: Well, yeah. My objection is, Q. Okay. So fundamentally, who -- who typed 18 as Dr. Lampotang has said, there's some confusion on 18 this list; you or your -- or the attorneys? [clearing throat] what he would receive versus what 19 19 20 A. Well --20 would be materials considered. 21 MS. LEWIS: You don't have to go into 21 MS. ZIMMERMAN: Okay, counsel. MS. LEWIS: So this is not a reflection of preparing part of your report, which this would be a 22 22 part of, in terms of who prepared what document would 23 all of the voluminous documents that have been 23 24 be protected. So beyond what you've said, --24 produced in this case that he may have received, so MS. ZIMMERMAN: Counsel, what --25 receiving something does not necessarily mean it was 25 Page 71 Page 73 1 MS. LEWIS: -- you don't have to go into something that was considered. 1 2 MS. ZIMMERMAN: I understand your 2 more details. 3 3 MS. ZIMMERMAN: Counsel, what rule do you objection. 4 invoke that says that I am not entitled to discover 4 I think that the answer from the witness 5 who prepared the document? 5 thus far is that he considers both document Exhibit 4 MS. LEWIS: 26(B)(4)(B) I believe. 6 6 and the references listed at the end of his report on 7 MS. ZIMMERMAN: He has just testified that Exhibit 2 [sic - Exhibit 3] to be documents he 7 8 this is not a complete list of the materials he has considered and/or potentially relied upon. He's also 9 had, so I --9 said that Exhibit 4 is not complete. 10 MS. LEWIS: Correct. 10 MS. LEWIS: Because it doesn't list every MS. ZIMMERMAN: -- need to understand who 11 single document that he has received, --11 12 wrote the document. 12 MS. ZIMMERMAN: But we are en --13 MS. LEWIS: "Materials considered" doesn't 13 MS. LEWIS: -- which there are thousands of 14 mean everything someone has received. documents in this case. 14 BY MS. ZIMMERMAN: 15 MS. ZIMMERMAN: And he has received all 15 Q. Are there documents that you received that 16 thousands of documents in this case? 16 you didn't consider? MS. LEWIS: Well, for example, in Walton 17 17 18 A. There's really a lot of material in this 18 alone, I don't even know how many documents there were in that case. So I'm just saying over -- I 19 case --19 O. Yes. 20 mean, there are thousands of documents. All -- All 20 A. -- and -the documents probably wouldn't fit into what is 21 21 "materials considered" as we understand that term. Q. And so --22 22 23 And I understand we're kind of joking about 23 MS. ZIMMERMAN: So counsel, is it your 24 24 position, as you sit here today, that Walton is it, but --25 separate from or combined with this MDL? Because A. Right. 25

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with respect to the letter that you outline in objecting to our subpoena, you refused to produce documents in connection with Walton and Johnson.

MS. LEWIS: Correct.

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MS. ZIMMERMAN: But now you're saying that there are additional documents that we potentially need to inquire about with respect to the witness's opinions in this matter, but that we're not allowed to ask what those documents are.

MS. LEWIS: No. That's not what I'm saying. What -- All Dr. Lampotang's trying to explain is, which is just a fact, is there are voluminous documents that have been produced. There's no way that his "materials considered" list would include every single document that has been sent to him.

MS. ZIMMERMAN: Well in fairness, counsel, it did include all of that the last time he issued a report, so we'll get to that later.

20 BY MS. ZIMMERMAN:

> Q. What I'm asking about here is with respect to the MDL report that's been prepared which comes with two attachments, a curriculum vitae and a list of materials considered. The materials considered is not numbered, it is about two and a half pages, and I

reading that permeates how I understand the problem, 1

Page 76

Page 77

2 how I interpret it --

3 Q. Okay. So --

A. -- and --

Q. -- with respect to this particular problem,

6 is it fair to say -- let's define "consider,"

7 documents or materials you considered as something you

8 read. Assuming that that's the case, that the doc --

9 the materials or documents you considered are any

documents you read in connection with this case, what 10

documents should be on this list? What are missing?

A. That's what I just tried to say. There --There are some I considered that I've been reading since -- apparently for this case at least it's been

15 since, you have said, 2016?

Q. Well since at least 2015.

A. Yeah. So -- So it's hard for me to say --

18 There -- There is a -- you -- you -- You get some

information from some papers, other papers, and that's 19

20 how you start to form your opinion, you look at the

21 data, you have objective data. And as I looked at

22 this, you know, it's -- these are the -- these are the

-- the documents that came to mind, but --23

O. And I understand that. I mean --MS. LEWIS: You didn't let him finish.

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Page 75

would like to know if this is a complete list of the materials that you've considered in offering the opinions that you intend to offer at this ca -- in this case.

MS. LEWIS: Which is a different question that you've asked previously.

You can go ahead and answer if you -- if you can.

A. The materials I have considered are -- are here, and like I said earlier, it may be there are others that I considered that I omitted to put in there.

Q. All right. So there may be materials that you considered that you omitted from --

A. Well --

Q. -- from this list.

A. -- what I'm trying to say is you -- you read material, you see some that says there is no correlation between this parameter and this parameter. I'm not there sitting and saying, okay, this is something that I need to set aside as -- and flag, say this is something that I will... because I didn't even know whether I would be writing a report at the time I was asked to start reviewing.

So -- So there is a lot of background

Were you finished?

Q. Well, but we're not going to just continue to -- I mean, he's been in school, he's an accomplished man, he's -- you've read a lot along, I'm sure, your -- your academic training and throughout your professional work, and many of the things that you've read in the past 25 years probably come to bear on lots of things that you encounter on a daily basis or in connection with expert reports.

But again what I am en -- what I am entitled to do here today, and charged with doing, is understanding the opinions that you intend to offer, and what the support and basis is of those opinions, and that is why there are citations to your report, and that is why there is a list of materials considered that are provided, so we can understand, is it -- do you have all the facts that you should have in rendering your opinions, or is there something missing that might change your opinions. And so when the list is not complete, that makes it difficult for someone to review to determine whether or not the opinions you intend to offer are reliable.

So again, as you sit here, the materials you have read and considered that appear on Exhibit 4, you said that they are -- that this is not complete, and

Page 78 Page 80 I'm asking what, if anything, you can remember that 1 He's an epidemiologist at the Keck School? 1 should be on this list that is not. 2 2 A. Right. 3 A. Okay. So I -- I read the Mont report, and I 3 Q. Do you know if you were provided with a copy read the Curtis abstract or publication or study that 4 of his report? 5 was referred in the Mont report. So I --5 A. I don't recall. I believe so, yeah. 6 Q. So those should both be on here? 6 Q. Do you know when you got copies of the 7 7 expert reports of the plaintiffs? And you list on And, you know, I should clarify one thing, 8 doctor. We're interested in those materials that you 8 Exhibit 4 plaintiff expert report of Michael Buck, read and considered by the time that you offered this 9 plaintiffs' expert report of Yadin David, plaintiffs' report. If you've -- If you've read, you know, a 10 expert report of Said Elghobashi, plaintiffs' expert 10 deposition this week, I think your time -report of William Jarvis, and plaintiffs' expert 11 11 12 A. Umm-hmm. 12 report of Dan Koenigshofer. Did they all come in one 13 Q. -- records suggest you read some depositions 13 batch to you? this week, that doesn't count because it wasn't a A. I can't remember. 14 14 basis for a report that you issued by June 2nd. Is Q. Okay. 15 15 that fair? A. Sorry. 16 16 17 A. Okay. 17 Q. Now with respect to the depositions that you Q. So what are any additional documents that 18 list here, do you know the date of the depositions? 18 you have read and considered through the time of June So, for example, the deposition of Troy Bergstrom, do 19 19 20 2nd when your report was signed and dated, that do not 20 you know when -- which deposition you read? 21 appear on Exhibit 4? 21 A. I don't remember. 22 22 Did you read the Mont report? Q. Do you know if it was the deposition taken 23 A. I don't know whether it was available at the 23 in the MDL, or in Walton, or in Johnson? 24 time, so. 24 A. I don't remember. I -- I don't 25 remember. Sorry. 25 Q. Okay. And you said a Curtis abstract. Do Page 79 Page 81 you know when you read that? 1 Q. Okay. Same question with respect to the 1 A. Recently. I don't know exactly when. 2 deposition of John Rock. [Clearing throat.] Excuse 2 3 3 Q. So your best estimate is that you read that me. 4 after the time your report was finalized? 4 Do you know which deposition of John Rock 5 A. Yes. 5 you were provided? 6 6 Q. Okay. Are there any other documents that A. It would have been I believe for the MDL. Q. Okay. And is that a --7 you read prior to finalizing your report that you did 7 not include in Exhibit 4? 8 That's your best guess? 9 A. Yes. I think I read Oguz. 9 A. Sitting here, yes. 10 Q. Okay. And then you list the deposition 10 O. Oguz? transcript of Al Van Duren, and it's listed twice. Do Any others? 11 11 12 12 you know when -- which deposition transcripts you were A. I --13 MS. LEWIS: And she's saying before June 13 provided with respect to Mr. Van Duren? A. Yes, there were -- there was two. 14 14 2nd. 15 THE WITNESS: Yeah. 15 O. All right. Do you know if he's been 16 A. Yeah, I think -- Yeah, I think that's --16 deposed. I think four times in this case? that's what I can recall. 17 A. No, I didn't know that. 17 18 Q. All right. Did you --18 Q. All right. Do you know if one of these is Were you provided with a copy of the report -- is a -- what they call a 30(b)(6) deposition, so he 19 19 20 of Dr. Michael Stonnington? 20 would be the corporate representative for 3M? A. Yes. I didn't know the 30(b)(6), but I know 21 A. Yes. 21 22 Q. And did you read that before your report was 22 he was the --23 23 Q. Corporate representative? finalized? 24 A. I can't remember. 24 A. Yeah. Q. What about the report of Dr. Jonathan Samet? 25 25 O. So one of these two notations for the

Page 82 Page 84 deposition of Al Van Duren is the 30(b)(6) deposition? 1 Q. The exhibits? 1 A. I believe so, yes. 2 2 A. -- the exhibits. 3 Q. All right. Did you read depositions in 3 Q. Well but with respect to Mr. Crowder you connection with your work in Walton and Johnson? listed out the exhibits, one, two, three, four, five, 4 5 A. I'm sorry. Can you repeat that? 5 six, seven, eight, nine, ten separate exhibits; 6 O. Sure. 6 correct? 7 Did you read depositions in connection with 7 A. Right. 8 your work on the Walton and Johnson cases? 8 Q. So with respect to Mr. Crowder it was 9 A. In the Walton case. 9 important to list that you had reviewed the deposition exhibits, but not with respect to the other Q. All right. Which depositions did you read 10 10 in connection with Walton? depositions that you read? 11 11 Are they on this list? A. No. I think, as I said, when I was 12 12 reviewing Crowder was when I was also writing the 13 A. Ah, no. 13 14 Q. "No"? You don't know? report, so I just included them. 14 A. This -- This is related to, I think, the Q. All right. And then turning to page 2, you 15 15 have a series of -- of studies listed. These are --16 16 17 Q. So it's your understanding that -- that the 17 Some of these studies also appear at the end of your Exhibit 4 is limited to only depositions that were report as references; is that right? There's some 18 18 taken in the MDL? overlap there? 19 19 20 A. Yeah. That's my understanding. 20 So, for example, Dr. Avidan --21 Q. All right. And is that your understanding 21 A. Yes. because you drafted this document? 22 22 Q. -- appears on page 2 of Exhibit 4, it also A. Yeah, I -- I supplied a -- a list of what I 23 23 appears on page 16 of Exhibit 2 [sic]; is that right? 24 had looked at. 24 A. Yes. 25 Q. Okay. 25 Q. All right. And you supplied that to Page 83 Page 85 counsel; correct? 1 THE REPORTER: Exhibit 3 is the report. 1 2 A. Yes. 2 Q. 3. I'm sorry about that. 3 3 And in any event, the 11 studies listed on Q. And then you have the deposition of Robert Crowder. Do you know when that deposition was taken? page 2 of Exhibit 4 are -- those are all the studies 4 5 You assume that's an MDL deposition? that you reviewed -- you read and considered in reaching the opinions that you outline in your report; 6 A. I don't know when it was taken. 6 is that correct? 7 Q. And you have a series of exhibits to Mr. 7 8 Crowder's deposition listed as well; is that correct? 8 A. Please repeat the question. 9 9 Q. Yes. 10 Q. Did you review any exhibits to any of the 10 There are 11 studies listed on page 2 of other deposition transcripts that you list on this 11 Exhibit 4. Those are all the studies that you 11 Exhibit 4? Al Van Duren, for example? 12 12 reviewed, that you read and considered, in reaching 13 A. Yes. 13 the opinions that you outline in your report; is that correct? 14 Q. But those exhibits are not listed on this 14 15 A. Yes. These are some of the -- some of the 15 report? 16 A. Yeah, I -- I -- I didn't include it. 16 studies, yes. Q. Okay. Is there a reason you didn't include 17 O. So --17 18 it? 18 "Some" or "all"? A. Probably because I read it before I was A. That's what I've listed here. As I said, 19 19 20 preparing my report, so -- And -- And I'm -- I'm -- I 20 there are others that I've read, but these are the am not facile with all these -ones that I thought I would include in there, so. 21 21 (Interruption by the reporter.) 22 Q. So these are the ones that you thought 22 A. I'm not facile with -- so I guess maybe I 23 23 merited disclosure; is that fair? assume that if I put deposition transcript that it 24 A. Yeah. 24

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also means I reviewed the --

Q. All right. And then the remaining documents

Page 86 Page 88 on Exhibit 4 are principally internal documents from 1 Q. Okay. Were there exhibits included with the 1 3M, including the Design History File of the -- both 2 document you were provided? the 505 and the 750; correct? 3 A. Not that I recall. 4 A. Which exhibit are you looking at? Q. All right. 4 5 Q. The one dir -- Exhibit 4 right in front of 5 MS. LEWIS: It was the order. MS. ZIMMERMAN: So not the motion. 6 6 you. 7 7 A. Okay. MS. LEWIS: Correct. 8 Q. So after the --8 BY MS. ZIMMERMAN: Q. You have not been provided a copy of 9 9 A. Yes. Q. Okay. And then you also read, it looks 10 plaintiffs' motion for punitive damages. Does that 10 like, two Court documents, one -- one is an Order 11 11 seem fair? Sustaining VitaHEAT Relevance Objections; is that A. I don't even know what "motion" --12 12 Q. You don't know? 13 right? 13 A. Yes. 14 A. -- means, sorry. 14 Q. And then also an order denying the 15 Q. Okay. So you have not also been provided 15 the 79-plus exhibits in support of that motion; have plaintiffs' objection to the Magistrate Judge's order 16 on VitaHEAT; is that right? 17 you? 17 18 18 A. Yes. A. No. 19 Q. Were you provided any other legal documents, 19 Q. Okay. And the only 3M internal documents briefs or orders or pleadings in this matter? that you have considered in offering your opinions in 20 20 A. In this matter, or -- or --21 this matter are those that are contained on Exhibit 4: 21 In this matter, or for the expert report? 22 22 correct? 23 Q. Well let's -- let's do both. 23 A. Yes. But again, this is -- there may be 24 So how about in this case generally? 24 things I omitted unintentionally, but yes, as far as I [Clearing throat.] Excuse me. 25 25 can tell, --Page 87 Page 89 A. Yes, there was -- there was another 1 Q. All right. 1 2 A. -- that's it. 2 document. 3 Q. What other document were you provided? Q. And then you have a few other notations with 3 respect to ASHRAE standards, and a document titled CDC 4 A. Can I ask counsel whether it's okay to share 4 5 that? Healthcare Associated Infection Progress, and that's the -- that's the last document listed on your 6 Q. Sure. We can go off record. 6 THE REPORTER: Off the record, please. 7 "Materials Considered"; correct? 7 (Discussion off the record.) 8 A. That is correct, yes. The CDC Healthcare 8 9 BY MS. ZIMMERMAN: 9 Associated Infection Progress. Q. Where did these documents come from? Q. All right, doctor. We took a short break so 10 10 A. The CDC Healthcare, I believe that came from you could confer with counsel. 11 11 12 Was there another legal document that you 12 the web. 13 were provided? 13 Q. Okay. And I mean more broadly, actually, 14 14 A. Yes. doctor. 15 Q. What is it? 15 Were these documents all provided to you by 16 A. It's -- I'm not sure I'm going to get the 16 counsel? name right, but it was punitive damage. 17 MS. LEWIS: Which ones; you talking about 17 18 Q. Oh, okay. Was it the plaintiffs' motion for 18 ASHRAE, or which ones? punitive damages? MS. ZIMMERMAN: Everything on Exhibit 4. 19 19 20 A. I'm sorry. I am not a legal person. 20 A. Well the stuff related to the case, yes. Q. All right. And that's --21 21 Q. Sure. 22 And by that you mean the expert reports, the 22 Do you know if it was an order from the transcripts, and the internal documents at least; 23 23 Court? A. I looked at it very briefly. The main thing 24 correct? 24 25 that jumped at me was punitive damage. A. Yes.

Page 90 Page 92 O. All right. How about the -- the articles 1 identification.) 1 that are listed on page 2, were those also provided to 2 2 BY MS. ZIMMERMAN: you by counsel? 3 Q. Before we get any further, are there any A. Not all of them. other documents with handwriting on them, with your 4 4 5 O. "Not all of them." 5 handwriting? 6 Which ones were provided by counsel? 6 A. No. 7 A. It's really difficult. Some of them were 7 Q. All right. So continuing on with page 2 of 8 already in my files, but I can't recall. Let me just 8 Exhibit 4, these 11 articles that you cite to, you'd say they are the ones that I know for sure I found. agree that the Albrecht article, "Forced-Air warming: Q. Okay. a source of airborne contamination in the operating 10 10 A. So Berrios-Torres, --11 room" was something provided to you by counsel; is 11 12 Q. Okay. B-E --12 that right? A. -- Loftus, Munoz-Price, and I believe 13 13 A. I think so, yeah. 14 Q. All right. And similarly with the -- with 14 Wagner. (Interruption by the reporter.) respect to the second document, Albrecht, et al 15 15 16 Q. So of -article titled "Forced-air warming blowers: An 16 17 A. And also, I believe, Neely. 17 evaluation of filtration adequacy and airborne Q. All right. So of the 11 articles listed on 18 18 contamination emissions in the operating room," that's page 2 of Exhibit 4, five of them you found on your something that was provided to you by counsel; 19 19 20 own? 20 correct? 21 A. That's my recollection. 21 A. Again, I believe so. I -- As I indicated Q. All right. Doctor, you're looking at a 22 earlier, I do have my own collection of papers that I 22 document right now that seems to have some handwritten download from time to time, so. 23 23 24 notations on it. What is that document? 24 Q. Okay. And the Bernards article and Avidan, 25 A. It's the same as Exhibit 4, but it's my 25 those were both provided by counsel? Page 91 Page 93 notes because I -- when I look at them I had no idea 1 1 A. I believe so. 2 what "789" means. 2 Q. All right. Same for Birgand, "Air 3 Q. So again there's more handwritten notes on 3 contamination for predicting wound contamination in stuff that hasn't been produced? clean surgery: A large multicenter study"; correct? 4 4 5 A. But I was intend -- I was intending to give 5 A. Yes, I believe so. it to you. This is just, if you tell me did you O. All right. And then finally the Van den 6 6 Broek article titled, "Epidemiology of multiple 7 review "2647," --7 8 O. Umm-hmm? Acinetobacter outbreaks in The Netherlands during the 9 A. -- I would --9 period of 1999 through 2001." That was also provided to you by counsel? 10 Q. So you know what the document is. 10 A. -- I would just say, to the best of my A. I believe so. 11 11 knowledge I assume I did, but. 12 12 Q. Let me ask you this: Prior to your So this is just a very quick reminder so involvement in this case did you have a collection of 13 13 this -- so I knew what -- what those numbers, those articles on patient warming? 14 14 A. I had a collection of articles on the 15 codes mean. 15 Q. Okay. When did you prepare the handwritten 16 reverse, which is patient cooling. 16 notations on this document? Q. Okay. So you did not --17 17 A. Yesterday. 18 18 A. Actually not patient, I'm sorry, athlete Q. All right. 19 19 20 MS. ZIMMERMAN: Why don't we go ahead and 20 Q. Athlete cooling. And is that in connection mark the handwritten version so that we have that for with some of the work you do with the NFL? 21 21 the record. A. Correct. 22 22 23 That's Exhibit 5, I think? 23 Q. Okay. 24 24 A. But it was inspired by the Bair Hugger. The THE REPORTER: Correct. work was inspired by the Bair Hugger. 25 25 (Lampotang Exhibit 5 marked for

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- 1 O. When did the work start?
- A. You mean the work with the NFL? 2
- 3 Q. Yes.
- A. It's in my CV, there is a grant and a year, 4
- so I -- I don't want to -- with the understanding that
- 6 I'm guessing and I don't have my CV in front of me, I think that was like 15 years ago. 7
- 8 Q. Okay. Was it around about the time Korey 9 Stringer died?
  - A. Yes. That was actually the inspiration.
- O. I wondered about that. He was a Minnesota 11 Viking --12
- 13 A. Yes.

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- 14 Q. -- who overheated on the field.
- A. Yeah. Actually before that there was a 15
- highly touted recruit who was a lineman called Auguste 16
- Eraste. He died in Flor -- at the University of 17
- Florida, and maybe Gabriel might remember that. 18

So that happened right before Stringer, so we had one-two punch.

- 21 Q. Yes.
- 22 A. And then we were just brainstorming saying
- what can we do about this. 23
- 24 Q. Right.
- 25 A. And then we said, you know, we are in

- 1 suit and that's really the thermal load that is --
- that challenges the players. And -- And so what we
- did is we carved channels in -- on the inside surface
- 4 that touches the players' chest and then we put a
- 5 bladder in front and a bladder in the back and then we
- 6 blow cool, dry air and that reaches the skin of the
- 7 player and allows the sweat to evaporate and therefore 8 cool them through the latent heat of vaporization of
- 9 the sweat.

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- O. Is it kind of like an individual air conditioner that's walking around in their --
  - A. Correct.

Because you've probably seen them at break they take their helmet quickly, but they cannot afford to do that. If you ever seen a football pad, it has three big buckles here for the -- so if there's an interception and they say, go, you cannot say, sorry, I'm still buckling my -- my pads.

- Q. Right.
- 20 A. So instead we have a quick-connect so that 21 when they jump off the be -- off the bench it will 22 just disconnect.
- 23 Q. All right.
  - A. And -- And there was -- NFL paid us to study
- 25 it, and we actually did the study and we showed a

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- anesthesia, what we do is control temperature, that's what we do. If we can control it up, we can control it down.
- Q. All right. And so -- And I think, if memory serves, Korey Stringer died in the summer of 2001, and so --
- 7 A. So I was about right, I said about 15 years 8 ago.
  - Q. Very good -- Very good estimate.

And so you've been working with the NFL and some of your colleagues on different modalities to potentially cool NFL players and other athletes; is that right?

- A. Actually it's beyond that. It is actually equipment now. It's part -- You see it on the bench.
  - Q. On the bench, too.
  - A. You see it on the sidelines, on the bench.
  - Q. And how do you cool them on the bench?
- A. There is a quick-connect that essentially 19 20 the football pad, to simplify it, is like a life
- jacket, and it's designed to absorb mechanical shock, 21
- but because it's a life jacket it has the equivalent 22
- 23 of a thick -- the thermal equivalent of a thick,
- three-piece suit, woolen three-piece suit. So imagine
- playing in the Florida sun at noon in a three-piece

- significant difference in core body temperature.
- Q. All right. So the modalities that you and your group worked on are effective at cooling the -the athletes; is that right?
  - A. That is correct.
- Q. All right. And I'm sure that they're very appreciative of that because they get to be very hot in the -- even in Minnesota, in the summer.
- A. Actually the first team that adopted it was 10 the Green Bay Packers.
  - Q. Well in Minnesota we would say that's because the Green Bay Packers are weak.
    - (Laughter.)

(Discussion off the stenographic record.)

(Lampotang Exhibit 6 marked for

16 identification.)

### BY MS. ZIMMERMAN:

Q. Is this --

Is Exhibit 6 a correct and complete copy of your curriculum vitae as -- as produced in connection with your expert report in this matter, doctor?

- A. I believe so. You handed it to me and I will accept it -- it's what was given to you, yeah.
- 24 Q. All right. So you -- you've -- you've 25
  - personally done computer modeling in the past; is that

Page 98 Page 100 dissertation in front of me, but I believe so, yes. right? 1 1 2 Q. All right. And you did that because it was 2 A. That is correct. 3 Q. And you agree that computer modeling can be 3 necessary and an appro -- and appropriate for you to disclose the methodology underlying your dissertation; accurate; correct? 4 A. With the appropriate preparation and 5 5 correct? 6 validation. 6 A. Yes. 7 Q. And you serve, from time to time, as shown 7 Q. All right. And assuming the appropriate 8 preparation and validation, computer modeling can be 8 in your curriculum vitae, as a peer reviewer; is that both accurate and very important in solving problems. 9 right? Would you agree with that? A. Yes. 10 10 A. Yes. And there's a third element, which is Q. And what does -- what does it mean to be 11 11 12 peer reviewed? 12 verification. 13 Q. Okay. And that's something that you've done 13 A. It means that your peers in the field of interest review the paper and determine whether it's 14 in the past. 14 -- it meets the required standard. 15 A. Yes. 15 Q. And in fact you used computer modeling in Q. All right. And -- And how does a peer 16 16 reviewer --17 connection with your dissertation; is that right? 17 A. A little bit, yes. 18 And you serve as a peer reviewer now; 18 Q. A little bit. That's -- I did not bring an 19 19 correct? 20 entire copy of your dissertation. 20 A. Yes. A. Umm-hmm. 21 Q. As a peer reviewer, how do you determine 21 Q. It is 400 pages; is that about right? 22 whether or not a paper meets the required standard? 22 A. It depends on the --A. That is correct. 23 23 Q. Okay. 24 24 It depends on multiple things, the -- part 25 A. Roughly. I can't remember. It was big. 25 of it is whether the hypothesis is -- is valid, it's Page 99 Page 101 Q. Well out of respect for the court reporter 1 clinically relevant; part of it is the methodology; 1 who does not want to carry these exhibits back, I and part of it is the interpretation of the results; 2 3 thought better than to print 400 pages. But --3 and part of it is assumptions that may have been made 4 But you used some computer modeling in 4 to conduct the study; part of it is the -- whether 5 connection with your dissertation; is that right? 5 there was Institutional Review Board, IRB, approval, 6 6 whether consent was obtained, whether --A. Correct. 7 Q. And as the -- as your supervisors were 7 O. Consent from? A. Consent from either patients or volunteers reviewing your dissertation paper, is one of the 8 9 things that they looked for transparency in what you 9 or students, if it's a learning outcomes study. were trying to accomplish? O. Okay. 10 10 A. I'm not sure if I understand your question. A. Part of it is whether HIPAA was observed, 11 11 12 Q. Okay. Did you --12 HIPAA, H-I-P-A-A, which is, I believe, health insurance portabili -- privacy and portability act. 13 For example, did you outline what equations 13 you were using in connection with your dissertation? So there are multiple elements. 14 14 15 A. I created the equations. 15 Q. All right. So as a peer reviewer, just so I 16 Q. Right. 16 understand, the things that you're looking for is what the -- the hypothetical -- let me get this right --And did your dissertation in fact include 17 17 the -- the equations that you were using? 18 what your hypothesis is; correct? That's the first 18 A. You are talking about the modeling part. thing? What the hypothesis is of the paper you're 19 19 20 O. Yes. 20 reviewing? A. Yes. 21 21 A. Correct. 22 22 Q. And you included, in the actual text of your Q. And you look to see if it's a valid dissertation, the equations that you were using with 23 hypothesis; is that right? 23 your modeling; correct? 24 A. Not -- Not a valid, it's a relevant 24 A. I graduated in 1992. I don't have the 25 25 hypothesis.

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- Q. Okay. 1
- A. If somebody writes a paper that is --2
- 3 Q. The ants go marching one by one, hurrah?
- A. Yeah, something like that. 4
- 5 O. So you look at -- you look at the
- 6 hypothesis, you see if it's valid and relevant; is 7 that right?
- 8 A. Yes.
- 9 Q. You look to see if there's proper
- methodology in the paper; correct? 10
- 11 A. Yes.

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- Q. You look to see what the interpretation is 12 13 of the results in that paper; is that right?
  - A. Yes.
- Q. You look to see what assumptions the authors 15 made in -- in preparing the paper; is that correct? 16
  - A. Yeah, you look at -- including in the assumptions are the, what we call the boundary conditions, if it's --
- 20 Q. Yes.
- 21 A. -- and then also the initial conditions.

22 And the other thing you also look like is

- 23 whether it is translational.
- 24 Q. "Translational."
- 25 What do you mean by "translational"?

- HIPAA, those are all things that you take into account 1 as a peer reviewer; is that right? 2
- 3 A. Right. And also, in some cases,
- 4 verification and validation.
- 5 O. All right. And how, as a peer reviewer, do 6 you approach verification and validation?
  - A. To be clear, this is not part of all papers.
- 8 Q. Right.
- 9 A. Some papers do -- do not have, for example,
- 10 code or modeling.
  - Q. Right.
- 12 A. So for verification you would look at what the authors said they were modeling, and how they 13 would model it, and then with verification you verify that it was done right, meaning according to what they said they would do. 16
  - Q. According to plan.
- 18 A. Yes.
  - Q. All right.
- 20 A. And with validation we look at the final
- 21 product, and if it was intended to do something we
- 22 look at it and say did it do what it was intended to 23 do.
- 24 Q. So when you -- the validation step, for
- 25 those studies where validation is a part of the paper,

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- A. Translational is now a -- one of the new 1 2 focus, know foci of the National Institutes of Health, 3 and it goes to the effect that much of the work that 4 we do is theoretical, and in the end a waste of the 5 taxpayers' money because the work doesn't bear on 6 patient outcomes.
  - Q. Okay.
  - A. So translational research is focused on research that bears on patient outcomes.
  - O. So translational research is research that is hopefully bearing on patient outcomes rather than research just for research sake?
  - A. Or research that is geared at fundamental
  - Q. Though I trust that you -- you think research that's geared at fundamental science is also appropriate.
    - A. Yes.
- Q. And so when you, as a peer reviewer, are evaluating a new paper and considering whether or not to publish it, the hypothesis, the methodology, the interpretation of results, the assumptions, including both initial conditions and boundary conditions, as well as things like the Institutional Review Board 24 approval, consent from a patient, implications of

- validation looks to see if the final product did what it was intended to do; is that fair?
- 3 A. Yes. It's whether you built the right 4 product.
  - Q. Okay.
- A. One was did you build the product right, 6 verification; and then validation is did you, in the 7 8 end, build the right product.
  - Q. Okay. You've designed or been involved with the design of various machines used in an operating room; correct?
- 12 A. I want to make sure I understand your 13 question. I -- I don't believe I have any equipment that has actually been commercialized that is used in 14 15 an OR.
  - Q. Okay.
- A. But I have features of equipment in an 17 18 operating room that I have written about that the manufacturer has implemented. 19
- Q. Thank you for the clarification. That is 21 helpful.
- 22 So some of the things that you've worked on 23 professionally are technologies or features

implemented into an anesthesia machine, for example.

25 A. Correct. And -- And -- And to clarify

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again, there is a product that I designed with other colleagues which did become a product, and that was a transport ventilator.

Q. Yes.

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A. And we did a -- essentially a bottoms up and minimal design which was actually quite successful commercially.

Q. And a transport ventilator, is that something that's used for patients that are moving from one room to another?

A. That, and also in an ambulance or in a helicopter.

O. All right. And ventilators are something that have been available for care and treatment of patients for many years; is that fair?

A. Depends what you call "many years." I think the genesis of it was -- or of what we consider modern ventilators was around in the '50s or '60s.

Q. All right. So there were some -- some type 19 20 of ventilators available, just hypothetically, 21 starting in the 1950s, and I gather that there have 22 been improvements upon ventilators since that time. 23 Is that fair?

24 A. Yes.

Q. All right. And you and your team have --

1 ventilator manufacturer licensed it and built it --

Q. And is that still --

3 A. -- and sold it.

Q. And that's still being sold today?

A. I don't know, because once the royalties end the University doesn't keep us abreast.

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Page 109

Q. Ahh. And did the royalties go to the

8 University?

A. Part of it.

Q. And part to you?

A. And the other coinventors.

Q. Okay. As you were --

As you were working on that, the improvements or the design for the transport ventilator, would you agree it was important for you to understand the environment of use in designing that product?

A. Yes. I -- I mentioned that already that, 18 19 you know, it's used in the -- Yes.

Q. All right. And you know, from your work on this case, that the Bair Hugger forced-air warming machine is intended for use in an operating room now; is that right?

24 A. Yes.

25 Q. And you'd agree, from an engineering

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have designed what you called a transport ventilator,

which is a newer technological advance with respect to 3 the ventilator; is that fair?

A. I would actually say it was not a technological advance, it was usability advance.

O. Did you make the ventilator smaller?

A. Not only did we make it smaller, which is a requirement for transport, we avoided the trap of taking a more sophisticated simulator -- I'm sorry --

10 ventilator, which is a fairly big ventilator about the

11 size of a kitchen oven, and that's what former

12 transport ventilators were, they had essentially

13 shrunk a very big piece of equipment but kept all the complex modes. And the people who use those transport 14

ventilators, they were having a hard time using all 15

the sophisticated features in these. They were not

really portable, they were more luggable, if you 17 18 remember the first laptops.

Q. Or cell phones.

A. Yeah. So what we did instead is we -- we just -- we didn't even use the high-end ventilators, we just basically said, what do we need, what is the bare minimum you need, and we designed that into a

very small box which I assembled on a Saturday morning

in my lab, and -- and I was surprised a Swiss

1 standpoint, that it is important for the designer of a

-- well frankly, of any device, to know where and how it's going to be used. Is that fair?

A. That is one of the considerations in the design.

Q. All right. And do you know --

Or you do know, I think from your report, that in an operating room special care is placed on the ventilation system. Is that fair?

A. You mean the air handling?

Q. Yes. The HVAC system. 11 12

A. Okay. Okay. Yes.

13 Q. All right. And there are specific

14 requirements with respect to filtration of that air; 15 correct?

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A. Yes.

O. If you know.

18 A. Yes.

19 Q. All right. And you cite to the ASHRAE 20 manuals in your report; correct?

A. Yes.

Q. All right. And there's also specific

23 requirements with respect to positive pressurization of an operating room; is that correct? 24

A. Yes.

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Q. All right. And you understand that the 1 purpose of the -- the air flow from the ventilation 2 system through the filters is to provide clean, filtered air to the surgical field; correct?

A. Yes.

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Q. And you understand that the purpose of that ventilation system is to push any particles that may be in the air towards the floor; correct?

A. Yes. It's a -- It's a vertical -- It's --Yes, umm-hmm.

11 Q. And the air enters at the ceiling of the room through diffusers, and then it exits the room 12 13 through returns usually in the perimeter of the room; correct? 14

15 A. Yes.

Q. And -- And those returns are on the floor; 16 17 correct?

18 A. Yes.

> Q. All right. And you -- you would agree that particles can contain bacteria. We talked about that earlier with respect to dust.

A. Yes.

THE WITNESS: May I remove my jacket? It's getting a bit warm.

MS. ZIMMERMAN: Yes, you may.

1 A. If -- If my recollection is right we discussed that dust could contain bacteria. 2

Q. Right.

And dust is a type of particle; you'd agree with that?

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A. Yes.

7 Q. And there are other types of -- of particles 8 that are -- are not dust; is that fair? Or are you 9 aware of any?

A. Yeah, there could be. Yeah.

Q. And if a particle, whether a dust particle or a different kind of particle, contains bacteria, you'd agree that that could cause an infection; correct?

MS. LEWIS: Objection, form.

A. It could if it lands in the wound in a sufficient number to cause an infection.

Q. And with respect to -- with respect to the number of -- the suffi -- what a sufficient number might be to cause an infection, you'd defer to an infectious disease doctor; correct?

A. That is correct. I -- I did read Dr. Mont's report, and he opined that one would not be enough.

And there are other factors too about whether an

infection would occur beyond the number of infectious 25

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1 THE WITNESS: Thank you.

2 MS. ZIMMERMAN: Why don't we take a -- five minutes, just stretch out and we'll turn on the air 4 conditioning?

THE WITNESS: I'm fine.

MS. ZIMMERMAN: Okay.

7 THE WITNESS: I just needed to get rid of my jacket. Thank you. 8

9 MS. ZIMMERMAN: That's fine.

10 BY MS. ZIMMERMAN:

Q. And doctor, you'd agree that if --

A. Thank you.

13 Q. -- if a device emits particles that contain bacteria, that could cause infections; correct? 14

MS. LEWIS: Objection, form.

A. Yeah. Could you define what you mean by 16 "particles"? 17 18

Q. Do you know what particles are?

A. Well you -- you asked me a question, and I'm 19 asking you to clarify your question. 20

Q. Right. So I said --I asked: If a device emits particles that contain bacteria that could cause infections. And we had previously discussed the fact that particles can contain bacteria; right?

organisms that land in the surgical site.

Q. All right.

MS. ZIMMERMAN: I'm going to object and move to strike as nonresponsive.

Q. You would defer to an infectious disease doctor with respect to what a sufficient number of bacteria would be in terms of what's required to cause an infection; correct?

A. Yes.

Q. All right. And is it your understanding that Dr. Mont is an infectious disease doctor?

A. Oh, I heard "doctor," I didn't hear "infectious disease doctor." I'm sorry.

Q. Okay. So you would -- you would defer to any doctor with respect to what an adequate bacterial contamination -- how much bacteria would be required to cause an infection?

A. Can you repeat your question, please?

Q. I will try.

I initially asked if you would defer to an infectious disease doctor as to what quantity of bacteria is required to cause an infection, and you said yes, and then you referred to Dr. Mont and some testimony he provided about one bacteria versus more than one bacteria. And I asked you if it was your

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understanding if Dr. Mont is in fact an infectious 1 disease doctor, and then we got this clarification about whether it's infectious disease doctors or any physician. So that's kind of how we got to where we 5 are.

You're not a medical doctor; correct?

- A. No, I'm not, but I teach medical doctors. I actually write guidelines for them.
- Q. Yes. And with respect to issues of infectious disease, you would defer to an infectious 10 disease doctor; correct?
- 12 A. Yes.

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- Q. All right. And you're not an expert in 13 aerobiology; is that correct? 14
  - A. No, I'm not.
- Q. All right. And you're not an expert in 16 17 microbiology; is that correct?
- A. No, I'm not. 18
- 19 Q. And with respect to issues concerning 20 orthopedic surgery, you'd defer to an orthopedic surgeon on proper practice and procedure; is that 21 22 fair?
- 23 A. Yes. I would defer to an orthopedic surgeon 24 regarding orthopedic issues.
  - Q. All right. And you would agree that -- that

1 Well you would defer to a doctor, an

2 infectious disease doctor with respect to issues about

Page 116

Page 117

- 3 how somebody is going to become infected. Is that 4 fair?
- 5 A. Yes.
- 6 Q. All right. And you're -- you're not going 7 to be offering any testimony at -- at trial in this 8 case about the mechanism of an infection fomenting in 9 a patient. Is that fair?
- 10 A. Yes. But as I mentioned, I have worked on 11 infection prevention.
- 12 Q. Yes.
- A. And if it's relevant, I may talk about that 13 because I have produced material in that field. 14
- Q. All right. Let me ask you this. What --15 What do you --16

17 What is your understanding of what a 18 surgical-site infection is?

- A. It's an infection at the surgical site.
- 20 Q. All right. Do you know what a
- periprosthetic joint infection is? 21
- 22 A. Yes.

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- 23 Q. What is it?
  - A. It's an infection when you do a -- you
- 25 replace a joint.

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if a device inside an operating room emits particles that contain bacteria, it's possible that that may

3 cause an infection: correct?

MS. LEWIS: Objection, form.

- A. The question was if a device emits particles that contains infectious organisms?
- Q. That contain bacteria, it's possible that may cause an infection.

MS. LEWIS: Same objection.

A. If -- It's possible --

Are you talking of surgical-site infections?

- Q. I'm just talking about infections right now.
- A. Okay. It's possible if -- if the patient is
- 14 -- has -- there are many factors that it's possible if the patient has a low immune system, et cetera, et 15 16 cetera.
  - Q. And those -- those factors that you're talking about with respect to a patient's susceptibility or ability to fight off an infection are not the same as being contaminated with bacteria. Do you understand that?

MS. LEWIS: Objection, form.

A. I -- No. I didn't follow your question.

24 I'm sorry. 25

Q. Sure. Is it --

Q. All right. And how is that different than a 1 2 surgical-site infection, if you know?

A. It's --

It's deeper, in general.

- Q. Is that the only difference?
- A. Well, as you said, I'm not a medical expert.
- I -- I know they are two different types of 7
- 8 infections, and I know what's -- was in this case was
- 9 the -- the joint infections.
- 10 Q. Okay. And at any rate, with respect to the difference between a SSI and a PJI, if there is a 11
- 12 difference you would defer to an infectious disease
- 13 doctor on definitions and that sort of thing; is that 14 fair?
- 15 A. Yes.
- 16 Q. All right. You'd also defer to them, I trust, on the mechanism of how it is that infection 17

18 came to be. Is that fair?

- A. For the prevention part I think I -- I have 19 20 created some materials, prior to this case, that may 21 -- that may be relevant.
- 22 Q. All right. What -- What materials are you

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- What materials have you created?
- 25 A. There are at least two, and actually there's

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a third one that's being patented -- that's being licensed. I'm sorry.

- Q. All right. And what -- what's the first one?
- A. The first one is a screen-based simulation of how to prep and disinfect the skin prior to surgical incision.
  - Q. Okay. What's the second?
- A. The second one is to help anesthesiologists primarily, because they are the ones who give the drug, how to dose and how to time the administration of cefazolin, I think the trade name is Ancef, and to make sure that the concentration, the effective concentration remains potent and effective if there should be any infection during surgery. And it also talks about not only the administration, but the mode of administration, whether you should give it bolus, which is take a syringe, fill it, shoot the whole thing, or whether you should give an infusion, which is you do --
- 21 Q. Drip.

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A. -- drip it in -- not drip it in -- with a syringe pump, or whether you should do both a bolus and an infusion. And it allows them to see, over time, the concentration and how it stays above or

protocol, I would not call it a protocol, it's really a way to help clinicians appreciate how, if they don't give the -- the prophylactic antibiotic within a given time window, it makes the patient susceptible to infection, and also that they should factor in patient weight when administering the drug.

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Q. Do any of those --

Do any of these three distinguish between SSIs and PJIs?

- A. No.
- Q. All right. You -- You reference in your report, and I guess your testimony just now reminded me of it, some of the -- well all three of these items that you testified about you've collaborated with -in some respects with -- with industry; is that fair?
  - A. Not the first one.
- 17 Q. Not the first one?
  - A. The first one -- I'm sorry. Not the third one, the urine --
  - Q. Okay.
- 21 A. -- we were not funded. I tried to get NIH 22 funding for it. Industry -- We did approach industry, 23 they -- there was a lot of mergers going on at the 24 time, so we were -- we were -- we were walking down

25 the wedding aisle, the -- the -- whatever, you know

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below -- or dips below the kill concentration.

- Q. All right. And what's the third?
- A. The third addresses one of the most common infections in the hospital, if not the most common, it's Catheter-Associated Urinary Tract Infection, it's commonly abbreviated as CAUTI, C-A-U-T-I. And we
- 6 believe, we -- and we have published on it, we believe 7
- we have found one of the mechanisms that create CAUTI.
- 9 and we have devised a physical device that disrupts 10 that mechanism.
  - Q. So are all three of these essentially protocols, or kind of an algorithm that a care provider would follow through in providing care and treatment for a patient?
- 15 A. The third one is not a protocol, it's a 16 physical device. It --17
  - Q. Okay.
- A. As I indicated, it's being licensed. It's 18 going into a commercial product that hopefully will 19 reduce urinary tract infection. And the other two, 20 these are not protocols that we came up with, it's 21 really -- the first one is the protocol from the 22
- 23 manufacturer, the skin prep. 24 Q. All right.
- A. And the second, it's -- it's -- it's not a 25

what I mean. But at the last moment they were nonresponsive and it turned out that the major manufacturer got acquired and everything got dropped.

O. Right.

A. So -- But yes. The second one was not with industry either, sorry. So the -- the cefazolin, that again was we noticed that there was a, in -- in our world we call it a gap, and -- a training and education gap --

But now a new outfit has licensed it.

O. Okav.

A. -- because people were not administering the antibiotic on time.

If there was a delay, like let's say the surgery was scheduled for 10 o'clock and for whatever reason the previous case is running late, the anesthetist, in anticipation of it starting at 10, may give the cefazolin at 9:05, but then the incision really occurs at 11, and that would be a breach of protocol.

- Q. All right.
- A. And -- But not simply a breach of protocol, 22 the concentration would have dipped. I'm sorry, I am 23 24 gesturing.

But if you look at a time plot you will see

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that the concentration over time is dipping, and it dips below the required concentration to kill any pathogens or organisms that get into the body.

- Q. And who did you work on that project with?
- A. I worked with a -- the colleague of mine who teaches what's called the Maintenance of Certification in Anesthesiology with me, and that's when we have anesthesiologists in practice spend a day with us, typically a Saturday, and we -- we teach them. And --
- Q. And they assisted you in developing the protocol?
- 12 A. There is no protocol, I want to clarify 13 that.
  - Q. It's just a training.
  - A. It's a visualization tool. Because when we were running the MOCA -- "MOCA" is Maintenance of Certification in Anesthesiology -- it became clear we've done, I don't know, 20 now, so we've looked at -- we've interacted with 200 anesthesiologists, both in private practice and academic practice, spent the whole day with them on a Saturday, and we put them in situations where it's not any more book knowledge, --
  - Q. I don't want to cut you off, but we do have a lot to get through.
- 25 A. Okay.

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1 involved with industry-sponsored research; is that 2 right?

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- A. That is correct.
- 4 Q. And -- And that, in your experience, is because industry has an interest in -- in learning 6 about their products sometimes; correct?
  - A. Yes.
  - Q. And you have had -- you've had occasion to both submit and review papers where some measure of support may have come from industry; is that fair?
- 12 Q. All right. Again, part of that is because industry has this incentive to study their products; 13 correct? 14
  - A. Yes.
  - Q. All right. And it has been your experience that "industry-sponsored research is truly independent" are your words on page 5; correct?
- A. That's the -- the construct, you know. 19 20 There have been cases of, as you probably know, of 21 academic fraud, --
- 22 Q. Yes.
- A. -- but that is the construct. That's the 23 24 construct under which I do my research when it's 25 industry sponsored.

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Q. I mean, I gather that this -- you know, that this screen simulation, is it something akin to kind of a video game or -- I mean, it is a simulation that

you do on a Saturday to try to --A. It's -- It's a modeled simulation, it's not a video game.

Q. Okay.

A. So there is a mathematical model behind it based on pharmacokinetic and pharmacodynamic, it's used --

(Interruption by the reporter.)

THE REPORTER: I'm sorry. There's a mathematical --

A. -- model behind it, and it's a pharmacokinetic and pharmacodynamic model, it's abbreviated PK/PD, thankfully.

And that's what drives the model. And --And to summarize, we created it because we saw a gap in the anesthesiologists who came and worked with us.

- O. And your efforts in creating this model and this simulation were supported in some way by the manufacturers, or industry; is that right?
  - A. For the cefazolin, no.
- Q. Okay. But you do note, in the middle of page 5, that you have from, time to time, been

Q. And when you're a peer reviewer that's one of the things, I assume, that your publications are 3 also looking at, there's, you know, disclosure rules with respect to, you know, funding and that sort of thing; is that correct?

A. Yes. That's required, yeah.

- Q. All right. And just generally speaking you'd agree that -- that the fact of a publication or a paper being sponsored in some way by industry does not, on its own, make that study invalid. Is that fair?
  - A. Yes, but there have been exceptions.
- Q. Yes. Absolutely.

But as a general rule it has been your experience, at least, that particularly with respect to peer-reviewed publications, that -- that the vast majority of -- of even industry-sponsored papers are -- are reliable. Is that fair?

- A. If the -- If the -- In general now -- It depends on the timeframe, too. This is an evolving environment.
- Q. Okay.

A. All right? So some papers, you know, like now the infamous studies where fat was blamed instead of sugar.

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- 1 Q. Yes. Also connected to Minnesota.
  - A. But there was no disclosure in -- in -- at the time disclosure was not -- I believe, I am not stating that for a fact, I may be proven wrong, but I
- believe at the time disclosure was not an integral
  part of the --
- 7 Q. Process.

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- 8 A. -- paper submission.
- 9 Q. And for many years it was not well
- 10 understood that tobacco would cause cancer; right?
- 11 A. Right.
- 12 Q. And I think in -- in that --

Well the researchers who have studied publications with respect to tobacco realized eventually that the risks associated with tobacco had long been known and perhaps not fully disclosed as a result of industry involvement in those studies; is that fair?

- A. I'm not -- I'm not familiar with that, --
- 20 Q. Okay.
- 21 A. -- so.
- Q. Did you ever read any of the --
- Do you subscribe to the New England Journal of Medicine at all?
  - A. I don't subscribe to it, but I read it from

- 1 respect to conflict of interest?
  - A. As an author, or as a reviewer?
  - Q. Both.
    - A. As an author, no. I always disclose.
- Q. And as a reviewer are you frequently finding that authors of papers that you are reviewing have not been forthcoming about a potential conflict of
- been forthcoming about a potential conflict ofinterest?
- 9 A. I'm not sure what you mean by "frequently," 10 but yes, I have -- I have had, in some instances
- 11 because I work in this area, I have had to tell the
- 12 editor -- When we review a paper there is what's
- 13 called comments for authors that the authors see, then
- 14 there is a part that says comments to editor that the
- authors do not see. And then usually in the comments
- 16 to editor in these -- in these cases, rather than
- 17 challenge the author, which is not my job, I would
- 18 tell the editor I am aware of this person, you know,
- 19 from being in -- in -- in the business in that area or
- 20 in that academic environment, that this person may
- 21 have a conflict.
- Q. All right. And approximately how many times
- 23 have you had a problem with an undisclosed conflict of
- 24 interest?25 A. I

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A. I don't know, three -- three, four times

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time to time.

Q. All right. Were you familiar with the academic scandal around Vioxx publications probably about 12 years ago? There was a paper submitted with respect to the risks use -- associated with the use of Vioxx, and eventually the -- the industry involvement in the study came to light and the New England -- the editors for the New England Journal of Medicine published what they titled an "expression of concern" with respect to a particular publication, essentially saying that they think that this was untoward and should have been disclosed.

You'd agree that -- that things like this are perhaps what has lead to the strict disclosure rules particularly in medicine that require the disclosure of any potential conflict of interest by authors. Is that fair?

- A. I'm not familiar with the Vioxx case you mentioned, but, yes, there have been egregious behavior that has prompted those disclosures.
- Q. All right. And since the time that you've been submitting peer-reviewed publications for consideration to various journals, and as a peer reviewer for various journals, is -- has -- have you run into significant problems with respect -- with

- 1 maybe over 25 years or over 30 years now. I don't 2 remember how long I've been reviewing papers.
- Q. All right. Fair to say it doesn't come up 4 very often?
  - A. Yeah.
  - Q. All right. It's serious if it does come up.
- A. Well in my case I don't know that it was serious or whether it was -- it was an omission. My job was to flag it to the editor and the editor pursued it, and usually it resulted in a disclosure.
  - Q. All right. Would you agree it's not appropriate to discount a study entirely based on concerns about funding for the study?

In other words, assuming that -- that the hypothesis is valid and relevant, that the methodology employed by the study authors seems to be legitimate, that the assumptions, both with respect to initial conditions and boundary conditions seem valid, and that the interpretation of the results is also appropriate, you wouldn't discount the conclusions reached by a study author merely because of who funded the study; would you?

A. If you have all of these elements in place where essentially you're describing there are no -- no red flags, and assuming the authors themselves didn't

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-- because when we write the discussion in a paper the

reviewers generally will say here are the limitations

of the study, here is what could have been done

better, was not done or could have been done

differently, and then based on that usually, upon 5

6 revision, the authors may alter their conclusions in 7 the discussion or in the conclusions.

So assuming the authors themselves didn't acknowledge that the study is -- has limits to how it can be applied and -- and cannot be used to change practice, for example, or to --

- Q. I think we're getting pretty far afield on where we started, doctor, and --
  - A. Okay.

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Q. -- you know, I apologize. Part of that is 15 16 my doing.

MS. LEWIS: But you interrupted him.

MS. ZIMMERMAN: Well we've been going for a page and a half, so we're going to get back to the questions at hand.

21 BY MS. ZIMMERMAN:

> Q. As you are reviewing a study as a peer reviewer you've testified that there are a number of things that you look at. You look to see if there is a valid hypothesis; correct?

1 A. Right?

> 2 So "valid" was the wrong choice of words, I 3 apologize. 4

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It's really is it a -- a meaningful

5 hypothesis, does it have -- if we can prove that 6 hypothesis, will it be meaningful.

Q. Right. Okay.

Meaningful, relevant, something to that effect.

- A. Right.
- Q. All right. So that's -- that's the first 11 12 step.
  - A. Yes.
    - Q. Okay.
    - A. Well it's not -- I'm sorry.

I don't have a checklist. I just read it.

It's -- Over the years as you review, you become, I

don't know, I guess what -- what it's called is 18

unconsciously competent. So you don't follow a 19 20 checklist, you just go through it and reach a

21 conclusion because you've done it enough that you --

22 vou are --23

Q. Okay. But so if you were trying to teach 24 somebody like me, a layperson, how you're going to

25 decide if a study either that someone else has

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A. The -- No. The hypothesis is never valid 1 because it's a hypothesis. Not to split words, 2 it's -- it's a worthwhile hypothesis. 3

Q. Okay. So we're looking for a worthwhile hypothesis.

A. And that may not be the right word. I'm --Like I think you described it better, what did you say, ants following ants or something, you know.

Q. Yeah. That's a childhood song, and I just was saving --

But so -- And I'm trying to use your words so that we're both on the same page.

A. Right.

Q. I'm trying to understand what it is as a peer reviewer that you look at to make sure that something is worthy of publication.

And I believe that you have talked about making sure that the hypothesis is both valid and relevant?

A. And -- And as I said, I misspoke, because a hypothesis --

Q. So it's a worthwhile --

23 A. -- by itself cannot be valid because it's a 24 hypothesis.

Q. Okay.

published, or that you are considering for peer -- for

peer-rev -- for peer-reviewed publication, you're

3 trying to decide is this something I -- I should

4 consider, or rely upon, or agree to publish, what are 5 the things we look for; what are the things you look

6 for?

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A. Right. And we've gone over that list. I was just saying this is not necessarily the first 9 thing I look at.

10 Q. Right. But -- So there is a meaningful or 11 relevant hypothesis.

12 You look to make sure that the methodology 13 is sound.

A. Umm-hmm.

THE REPORTER: Your answer, please?

16 A. Yes. Yes.

THE WITNESS: Sorry.

18 Q. You look at --

And that includes initial conditions; 19

20 correct?

- 21 A. Initial conditions, boundary conditions,
- 22 simplifying assumptions.
- 23 Q. And you look at the interpretation of the 24 results that the authors provide?
- 25 A. Yes.

Confidential - Subject to Protective Order Page 134 Page 136 Q. You also consider whether it's Institutional 1 Q. Yes. 1 Review Board approved; is that right? 2 2 A. -- now your model, you know, you've probably 3 A. Yes. 3 heard of garbage in, garbage out. 4 Q. Whether the patient or participant has 4 Q. Yes. 5 provided consent; is that right? 5 A. So validation is a way for you to catch user 6 A. Yes. 6 error, improper simplifying assumptions, improper 7 boundary conditions, and improper initial conditions, Q. Also whether or not HIPAA has been complied 7 8 8 because these all affect the output of the model. with; is that right? 9 9 Q. Would you agree that there's a difference A. Yes. 10 Q. Then you look to see if, at least for some 10 between code validation and verification? studies you look to see if it's translational; A. Yes. Validation and verification are very 11 11 12 correct? 12 different. A. Yes. 13 13 O. What is code validation? 14 14 A. Are you --Q. Which means focused on research that bears on patient outcomes; is that fair? 15 Q. If you know. 15 A. I'm not an expert in code, so I know what 16 A. Yes. 16 17 Q. And there are -- there is some research 17 validation and verification is, but I would assume that's not going to be translational. It may still be 18 code vali -- I don't know, so I won't -- I won't 18 valid, but it's not translational research; is that 19 venture a guess. 19 20 right? 20 Q. All right. 21 A. Yes. 21 A. I don't know. 22 Q. Okay. And then you look for verification; 22 Q. And so you're not going to be offering any 23 23 opinions in this matter about whether or not a code correct? 24 A. Where it's appropriate, yes. 24 has been appropriately validated; is that right? 25 Q. All right. And that means was the study 25 A. The code itself, no. But the -- on the Page 135 1 1

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done the way it was planned to be done; right?

A. Or was the modeling done the way it was planned to be done.

Q. Okay. And then the last step I think that we talked about is that for some studies validation may be involved as well; correct?

A. Yes.

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Q. And that means essentially did you build the thing you thought you were going to build; is that right?

A. Yes. But there is -- For example in a learning outcomes study we would validate whether somebody using that training tool, for example, the skin prep simulator, has better skills after using the simulator, which would -- means, you know, it's -it's -- we have validated that the tool is effective.

In the case of a model we would validate whether the prediction of the model match the physical experiment, the corresponding physical experiment.

Q. Is that required, a physical validation of all models?

A. I think it's good engineering practice because there are many ways a model can create flawed output, and one way is simply user error, if you put Centigrades instead of Fahrenheit --

concept of validating the output of a model, as a mechanical engineer I think I can speak to that.

3 Q. All right. And is that something that you 4 have disclosed in the expert report that you provided in this case?

6 A. No. This is a conversation we're having 7 now, so.

Q. Okay. Well, and I am trying to understand, I mean, I -- I know generally from looking at your dissertation that you validated code in connection with that 20-some years ago; is that right?

A. Okay. Maybe I misunderstood your question. Yes, I wrote code, and I validated the output against a mechanical test lung.

O. Okav.

(Interruption by the reporter.) (Discussion off the stenographic record.)

Q. But at least in connection with your work in the Bair Hugger case, you have not been asked to opine one way or the other if any particular expert's code has been appropriately validated; is that correct?

A. Let me make sure I understand your question. What do you mean by "code has been validated"? Are vou talking of whether the -- the way the code was

Page 138 Page 140 done, what equations were made and all that, or are finalized your expert report in this matter; right? 1 That's why it's on Exhibit 4, it's one of the things you talking about the overall output? 3 Q. Well when you talk about the -- you know, 3 that was listed as a material you considered; correct? the steps that you go through in understanding or 4 A. Yes. 4 5 evaluating a piece of literature, expert literature, 5 O. And there is -- there is no point in your 6 the final two steps that we've discussed are 6 written report where you are critical of Dr. 7 verification, that you did what you planned to do; 7 Elghobashi's report; correct? 8 8 A. Yes. right? 9 9 Q. All right. Are you a member of the -- the A. Umm-hmm. 10 THE REPORTER: Your answer, please? 10 Academy of Engineers? 11 Q. And then for some --11 A. No. A. Yes. Yes. Q. Okay. Were you provided expert reports from 12 12 any of the other defense experts in this case? 13 THE WITNESS: Sorry. 13 14 A. Was I provided expert's reports from other O. And then --14 defense experts? 15 And in some instances also validation; 15 Q. Yes. 16 correct? 16 A. Yes. 17 A. Yes. 17 Q. Who? 18 Q. All right. And then, you know, turning I 18 guess back to the front page of Exhibit 4, which is A. I think Mont. 19 19 20 the materials that you've considered, you were 20 Q. Okay. And that was after the time of your provided with expert reports from five of plaintiffs' 21 21 report? 22 22 experts; is that right? A. I believe so, yes. 23 A. Yes. 23 Q. Were you provided drafts of any expert 24 Q. And that includes Dr. Said Elghobashi; 24 report for 3M and Arizant prior to finalizing your 25 25 report? correct? Page 139 Page 141 A. Yes. 1 A. I can't remember. 1 Q. Do you know him, by the way? 2 Q. All right. And I take it if you were 2 relying in any way on any expert report disclosed by 3 4 Q. All right. You haven't worked with him at 4 the defendants it would be either as an appendix to 5 the NIH at all? 5 your report or on this list of materials considered; 6 6 And he's not at the NIH. correct? A. Right. I don't know -- Oh, I guess that was 7 A. He's not NIH, --7 8 Q. No. a dep -- yeah, that was a deposition. I did -- And I 9 A. -- and that's why I was frowning. 9 don't know who Crowder is, whether he's defense or 10 10 O. Okay. plaintiff. A. No. No. he's not at the NIH. Q. All right. And would it surprise you to 11 11 12 But no, I have not worked with him. 12 know that he was a corporate employee, not an expert? 13 Q. All right. Have you --13 A. I guess that makes sense. Q. Okay. Were you provided, at any time, the 14 Are you aware of his reputation at all? 14 expert report of Dr. Thomas Kuehn? 15 A. I was not aware. 15 16 Q. Are you now? 16 A. Yes. Q. All right. When were you provided that? 17 A. Yes. 17 18 Q. All right. And what is your understanding 18 A. I don't remember. of Dr. Elghobashi and his reputation? Q. Sometime after your report was finalized? 19 19 A. I think the main criteria that jumped at me 20 A. I don't remember. 20 was he's in the National Academy of Engineers. Q. Okay. At any rate, it doesn't appear on the 21 21 Q. All right. And that's a big deal? list of materials considered; correct? 22 22 23 A. Yes. Umm-hmm. 23 A. (Witness reviewing exhibit.) Looking at 24 Q. All right. And at any rate, you had a copy 24 this, it doesn't seem to be the case.

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of Dr. Elghobashi's report prior to the time that you

Q. All right. What about Michael Keen from

Page 142 Page 144 Q. Okay. And actually, you know, with respect Canada, have you seen his report? 1 1 2 2 to Dr. Thomas Kuehn, were you provided a copy of his A. Yes. 3 Q. All right. And was that provided to you 3 deposition at all? after you completed your report? 4 A. I don't remember. I don't think so, but I 4 5 A. I don't remember. 5 don't remember. 6 Q. Have you seen his deposition? 6 Q. So do you know, as you sit here today, that 7 7 he testified his agreement that his data was also 8 Q. Did you see Dr. Kuehn's deposition? 8 unreliable? 9 A. I can't remember. 9 MS. LEWIS: Objection, form. 10 Q. All right. What about Dr. Settles, were you 10 A. I -- I don't remember reading his provided with a copy of his report? 11 11 deposition, so. 12 Q. Okay. Any other videos besides the video in 12 A. Yes. O. All right. Were you provided with a copy of 13 13 the Netherlands and the green smoke video? his deposition? A. Right now I can't remember. 14 14 A. I don't remember. 15 Q. And those of course are not disclosed on the 15 Materials Considered list; correct? There's nothing Q. Do you know if you got a copy of Dr. 16 16 Settles' revised report? 17 17 about any videos on your Exhibit 4? A. I don't know. 18 A. Let me look. (Witness reviewing exhibit.) 18 Is this Exhibit 4? Q. Okay. What about Dr. John Abraham, were you 19 19 20 provided with a copy of his report? 20 Q. Yes. 21 A. Yes. 21 A. Okay. (Witness reviewing exhibit.) No. 22 Q. All right. And have you -- have you seen 22 Q. Why not? the videos that Dr. Abraham has prepared? 23 A. I -- I looked at them a long time ago. 23 24 A. No. 24 Q. Is it something that you relied upon in 25 offering the opinions that you're -- contained in your 25 Q. Have you seen any videos about issues in Page 143 Page 145 this case? 1 1 report? 2 A. This goes back to my difficulty with "rely A. Yes. 2 3 on." I -- I've looked at them, and it's -- it's not a Q. What videos have you seen? 4 A. I think there was one that was done in the 4 -- How do you say that? 5 Netherlands, and then there was the green smoke video, 5 Q. Well it's not complete; right? A. I'm sorry? 6 whatever it's called. 6 7 Q. It's not complete; right? Q. Hot air rises? 7 A. I can't remember. I'm sorry. 8 8 A. No. What I'm trying to say is there is a 9 Q. Have you --9 lot of documents that I've read, and I cannot say this 10 Are you aware, by the way, that Dr. Settles, -- this one is ex -- I was not keeping a track of what 10 he had to provide a revised report because some of his I'm going to right in deposition, I was just reviewing 11 11 data were not reliable? 12 material as it came, and this is my effort to document 12 MS. LEWIS: Objection, form. 13 13 it. O. Because he determined some of his data was 14 14 Q. All right. And counsel wasn't able to help not reliable? provide you a more complete list of all the materials 15 15 A. I'm not aware of that. 16 that you were provided? 16 17 Q. Okay. And you don't know, as you sit here, A. Well, I think you have to -- to ask counsel 17 that question. I don't know what to say. 18 which version of his report you were provided; is that 18 Q. All right. 19 right? 19 20 A. That's correct. 20 A. I'm sorry. Q. So the videos that you saw, you don't Q. And you saw a copy of the report that was 21 21 22 believe you saw Dr. Abraham's video, you saw a video 22 disclosed in the Walton case; right? that you think was made in the Netherlands, and one 23 A. I saw a copy of the report? 23 24 about smoke rising; is that right? 24 O. Of your --25 A. The green smoke, yeah. Of your expert report that was prepared in 25

	P 14C		D 140
1	Page 146	1	Page 148 THE VIDEOGRAPHER: Can we go off the record
$\begin{bmatrix} 1 \\ 2 \end{bmatrix}$	Walton; correct?	1 2	THE VIDEOGRAPHER: Can we go off the record
2 3	A. Yeah. I prepared it.	3	to change disc?  MS. ZIMMERMAN: Sure.
	Q. All right. And did	4	(Discussion off the record.)
4	And did you prepare the list of ite	5	(Luncheon recess taken at
5	documents considered in that report as well?  A. Well that's even further back in time, so	6	· ·
6 7		7	approximately 11:59 a.m.)
8	Q. Right. A I can't remember.	8	
9		9	
10	Q. Okay. Would it surprise you if counsel, Ms. Cohen or her office, prepared that list of items	10	
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12	considered with respect to the Walton litigation?	12	
13	A. I doubt it because I wrote the report, so,	13	
	but it's it's a long time ago, so you're asking	14	
14 15	me to speculate, or to go back to memory.  Q. Yeah. So is it your your testimony that	15	
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16 17	you did the same you followed the same procedure in preparing the report here in the MDL and also in the	17	
18	Walton matter?	18	
19		19	
20	<ul><li>A. Yeah, pretty much.</li><li>Q. All right. And that that holds true also</li></ul>	20	
21	for the Materials Considered, you did the same thing	21	
22	here that you did for the Walton case?	22	
23	MS. LEWIS: Objection, form.	23	
24	A. What do you mean by "same thing"?	24	
25	Q. Well you're following the same protocol.	25	
23	Q. Wen you're following the same protocor.	23	
	Page 147		Page 149
1	You prepared a report in each case, and you prepared a	1	AFTERNOON SESSION
2	list of of end notes or references at the back of	2	(Deposition reconvened at
3	each report. Did you also provide a list of materials	3	approximately 12:34 p.m.)
4	considered for each report?	4	BY MS. ZIMMERMAN:
5	A. I don't remember.	5	Q. All right. We'll try and get going again
6	Q. Okay. But in any event, it's your practice	6	here. I trust you were able to have a little bit of
	to prepare the list of materials that you've	7	lunch?
8	considered when you pre when you provide a report	8	A. Yes. Thank you.
9	like this; is that right?	9	Q. Right before the break we were talking about
10	A. I I indicate what I am reviewing as I'm	10	the materials that that you've considered, and it's
11	writing the report, yes.	11	something that we talked about quite a bit this
12	Q. Okay. And you did you did that here in	12	morning.
13	this in this case, we call it the MDL, the	13	I'd ask you to turn to the back of your
14	multidistrict litigation; right?	14	report, which I think is Exhibit 3.
15	A. Yes.	15	A. Oh.
16	Q. And you did it once previously at least in	16	(Reporter indicating.)
17	the Walton case as well; correct?	17	THE WITNESS: Thank you.
18	A. I don't remember.	18	Q. And you have about a little more than a
19	Q. Okay. So that report was done a little less	19	page, page and a half of materials referenced at the
20	than two years ago; does that sound about right,	20	end of your report. Do you see that? Appearing on
21	around this time in 2015?	21	pages 16 and 17.
22	A. I don't remember. I'm sorry.	22	A. (Witness reviewing exhibit.) Yes.
23	Q. Okay.	23	Q. All right. Now you I asked you some
24	A. I think that there are dates on the report,	24	questions this morning about independent research that
25	SO.	25	you did in this case, and you identified five articles

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- that you had -- I'm sorry, six articles that you had
- discovered on your own through independent research.
- 3 Do you recall that? 4
  - A. Yes.

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- 5 Q. All right. What did you search for when you 6 did this independent research?
  - A. Forced-air warming, I'm --
  - I don't recollect, but forced-air warming,
- 9 Bair Hugger. Some of it, you know, the -- There's
- another one I think I found by myself, which is the 10
- Moon reference. 11
- 12 Q. The Munoz-Price article?
- A. No. The Moon, the last one on page --13
- Q. Oh right, okay. 14
- A. -- 17. 15
- Q. So that one you found as well. 16
- 17 A. Well I think it was discussed, but the paper
- 18 had not come out.
- Q. It's pretty new; right? 19
- 20 A. Yeah. So I found the paper.
- 21 Q. Okay. So when you talk about the
- independent research that you did, did you do that on 22
- 23 PubMed?

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- 24 A. Yes, I did some of it on PubMed.
- 25 Q. All right. Where else did you do research

Anesthesiology for quite awhile now, and some of those articles are in Anesthesiology, the journal. 2

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- 3 Q. Okay. So let's get back, though, to what
- 4 you did here. You did some research independently on
- 5 forced-air warming and on Bair Hugger, and you did
- 6 this research on PubMed, and on Google Scholar, and on 7 Google; is that right?
- 8 A. Yes. And then also in the course of my
  - work, like, for example, the CDC Guidelines, this is
- 10 something that came out in March, and I'm on a
- 11 Anesthesia Performance Improvement Committee, and that
- 12 was brought up and I looked at it, I say, this is
- interesting, it has -- it has bearing in this case. 13
- 14 So some of it I encountered through my day-to-day
- 15 work.

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Q. Okay. Taking just a step back.

17 You said, I think, that you subscribe to the

- 18 journal of anesthesia; is that right?
  - A. Anesthesiology.
- Q. Anesthesiology. 20

Do you consider that authoritative with

- 22 respect to publications in that journal?
- A. Not everything is -- is authoritative. Some 23
- 24 articles I believe get published even though they may
- 25 -- the review process sometimes you get articles that

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besides PubMed?

- 2 A. Google Scholar.
- 3 Q. Okay. Anywhere else?
- 4 A. Google itself, and.
  - Q. Anything else?
- A. And then in some cases I -- I used my own 6
- 7 library of -- of references.
- Q. All right. But when I asked you earlier 8 this morning about whether you, prior to being
- involved in this case, had a trove of articles with 10
- respect to patient warming I believe your answer was 11
- 12 the -- actually the opposite, it was about patient
- 13 cooling. Is that a fair summary of our conversation
- 14 about that?
  - A. That's -- That's correct, yeah.
  - Q. All right. So you -- did you --

You did not have, then, articles with

respect to patient warming prior to becoming involved in this case; is that fair?

- 20 A. I -- I cannot tell you one way or another.
- I -- I know I have a lot of articles, you know, in my 21 office, a lot of journals. 22
- 23
- Q. But you don't know when you received them or 23 24 when you found them; is that right?
- A. I've been receiving the journal 25

- Page 153 are not authori -- are not -- either are not sound, or
- 1 later are proved not to be sound, and then it's not a
  - -- some papers parts of it may -- may bear the test of
- 4 time, other parts may not -- may not do so.
  - Q. But generally speaking you -- it's been your experience that articles published in anesthesia are authoritative?
- 8 A. I already answered that. I believe the --9 the journal is respected in the field, but not
  - everything that comes -- that is published in
- anesthesia is authoritative. 11
  - Q. In your opinion.
- 13 A. In my opinion.
  - Q. Okay. Do you know Dr. Sessler and Dr. Kurz?
  - A. I know Dr. Sessler. I -- I have read Dr.
- 16 Kurz' work.
  - O. I don't see either Dr. Sessler or Dr. Kurz's work cited in your paper, in your report. Why not?
    - A. I -- It's an omission.
  - O. It's an omission?

Is it something that you considered, or is 21

- 22 it something that you're relying upon? A. I -- I -- I really am struggling with that
- 24 "considered" versus "relied upon," so I -- I -- I read
- 25 it.

Page 154 Page 156 Q. Well respectfully, doctor, whether --1 read that long ago. 1 Q. Okay. So you did a study -- Or pardon me. 2 whether we're communicating clearly about the 2 3 distinction between "considered" and "relied upon," 3 You did independent research on forced-air neither the Sessler articles nor Kurz appears on warming and on Bair Hugger in PubMed, in Google 4 either the citations in your report or on the 5 Scholar, in Google, and generally in your office where 6 Materials Considered; correct? 6 you have some articles of some kind. Is that fair? 7 7 A. Yes. A. Correct. 8 8 Q. Is there any other place that you did Q. All right. Do you consider Sessler a leader 9 in hypothermia research? 9 research for this case? 10 A. Yes. 10 A. Well some of it was not research, as I mentioned, it was just my day-to-day work I 11 Q. All right. Do you --11 Do you likewise consider Dr. Kurz a -- a encountered material that was relevant to the case and 12 12 leader in hypothermia research? 13 13 I included it. A. I don't know what you mean by "a leader," 14 14 Q. All right. And -- And does that appear both but her paper is widely cited. on the citations at the end of your report and the 15 15 Q. All right. And you've read it? Materials Considered? 16 16 17 A. Yes. 17 A. (Witness reviewing exhibits.) Yes. Q. And you read it prior to your involvement in 18 Q. And where does it appear? 18 this case, or as a result of your involvement in this A. Materials Considered, page 2, --19 19 20 case? 20 Q. All right. 21 A. I can't remember. 21 A. -- Berrios-Torres. 22 Q. And that would be Berrios-Torres, Loftus, 22 Q. All right. Are you familiar with the Sun article on efficiency of forced-air warming? 23 23 Munoz price, Neely and Wagner. Are those the ones 24 A. "Sun"? 24 that you identified? 25 Q. Yes. 25 A. Okay. I think you mixed two questions here. Page 155 Page 157 A. How do you spell that? I was replying to which one did I encounter 1 1 Q. It's a 2015 article spelled like the orb in 2 through my day-to-day work -the sky, I believe, S-U-N. 3 Q. Okay. Which is your --3 4 A. -- in the hospital. 4 A. I don't remember reading Sun. 5 Q. All right. Would it surprise you that there 5 Q. Which is your day-to-day work you had was an article by Sun on the cover of Anesthesiology 6 6 encountered? A. The one Berrios-Torres --7 in February of 2015? 7 8 A. I don't understand your question. I'm 8 O. Okav. 9 9 A. -- was -- I encountered that through my work sorry. 10 Q. Well you're -- you subscribe to the journal with the Anesthesia Performance Improvement Committee. 10 Anesthesia: correct? 11 11 12 A. Yes. 12 A. It had just come out, some of my colleagues were discussing it, and when I looked at it I saw that 13 Q. All right. And so I was asking you if you 13 were familiar with the author -- pardon me -- the 14 it recommended normothermia as a means to prevent 14 article authored by Sun in 2015, and -- which appeared surgical-site infection. And -- And I was given a 15 15 on the cover of Anesthesiology in February of 2015. 16 copy, and -- and then I went and downloaded the actual 16 Are you familiar with that article? 17 electronic copy. 17 18 A. No. 18 Q. All right. And do you -- do you consider that particular article authoritative? Q. All right. You understand that Dr. Sessler 19 19

coauthored that article?

A. I -- I'm not familiar of the Sun article, so

Q. Okay. So you didn't read the journal

A. I -- I can't tell you what I read or didn't

I cannot speak to who was the co-author.

article, or the edition in February of 2015?

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A. As we discussed already, parts of it are authoritative, parts of it my colleagues actually were pushing back on it, and so -- but it is -- it comes from the Center for Disease Control, which is well respected.

Q. All right. And you generally consider the

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recommendations from the Center for Disease Control to 2 be authoritative?

3 A. I would have to answer that question some of it maybe. As I said, when I was at that Anesthesia 4 Performance Improvement Committee meeting, the 5

6 clinicians in the room disagreed with one of the

recommendations, I don't remember which one now, and 7

8 that's why the actual printout was brought to that meeting and handed to the participants, to the

committee members, and I'm one of the committee 10

members. And -- And in reviewing it, what --11 12

Q. So let me just stop you, because the question pending was, are yo -- and do you generally consider the recommendations from the Center for Disease Control to be authoritative?

And we've now moved into a committee meeting where a printout was brought.

A. Well I was trying to explain that -- give an example that the committee members, and I'm using that as an example, so, and I already said earlier that not everything that comes out from the CDC is necessarily authoritative.

23 And -- And I gave -- And I was in the 24 process of giving an example that my clinical colleagues questioned one of the recommendations in

Q. All right. And what about the Belani paper? That's not listed either on the list of references or on the list of materials you've considered. Why is that?

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A. The -- Those papers, the authors, at the end they -- not "at the end."

The authors, as discussed earlier, they explained some of the limitations of what they did --

9 Q. So that's not quite my question, though, 10 doctor --

MS. LEWIS: Well he didn't finish, Genevieve. At least let him finish what he was saving.

MS. ZIMMERMAN: No thanks, counsel. I'll ask the questions here.

BY MS. ZIMMERMAN: 16

> O. So my questions are: You do not cite anywhere on your report of materials that you rely upon, Legg, Dasari Belani, Reed, Leaper, many other forced-air warming studies. Likewise, and it seems from -- from your response to my question before counsel interrupted, you're familiar with these studies; is that fair? You've read them before?

A. Yes.

Q. All right. So at some point you have been

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that Berrios-Torres paper. 1

Q. Okay. So it is your opinion that not everything that comes from the CDC is necessarily authoritative. Is that fair?

5 A. Yes, not everything is necessarily 6 authoritative. It is a respected body. 7

Q. Right. In your opinion.

A. Yes.

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Q. Okay. And when you're evaluating

recommendations from the CDC, for example, one of the things that you would look to in deciding whether you agreed with the recommendation or not is the basis for

13 -- from which the recommendation comes; correct?

A. Partly the basis, and partly clinical input.

Q. All right. So turning back to the -- the searches that you did, your independent research, I don't see -- I don't see the Legg study anywhere on either your list of authorities at the end of your report, or on the list of materials you considered.

20 Why is that?

> A. I presume most likely because I read it a long time ago.

Q. All right. What about the Dasari paper? I don't see that listed either.

A. I think that's -- that's the same.

provided or found the Legg study; is that fair?

A. Yes.

Q. All right. The Dasari study, you've seen that before?

A. Yes.

O. You've read it?

A. Yes. 7

8 Q. It was provided to you?

A. I can't remember, but yes, I --

Q. All right. Same thing with the Belani 10 study. That's something that you've read before; 11 12 correct?

A. Yes. 13

14 Q. And you've read the Reed study before; 15 correct?

A. Yes.

Q. And are you aware that -- that 3M -- 3M has 18 recently hired as a -- or funded research with respect to -- to Mr. Reed and the issues around forced-air 19 warming?

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A. What was the question?

22 Q. Are you aware that 3M has -- has, in 2016, 23 retained and funded Dr. Reed's studies going forward 24 with respect to forced-air warming?

A. I was not aware of that.

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Q. All right. And the Leaper study, have you seen the Leaper study?

- 3 A. Yes.
- 4 Q. All right. And none of these studies are
- 5 listed in -- in the references at the end of your6 report; correct?
  - A. (Witness reviewing exhibits.)
- Q. And we'll get to -- we'll get to Exhibit 4 in just a minute, but --
- 10 A. Yeah.

7

- 11 Q. -- none of those studies are listed as
- 12 references to your report; correct?
- 13 A. Yes.
- Q. And -- And none of these studies are listed
- on Exhibit 4, the materials you've considered, either; are they?
- 17 A. (Witness reviewing exhibit.) No, but I do 18 mention the Albrecht study.
- Q. And are you aware that Dr. Legg has been deposed in this case? Mr. Legg, I should say.
- A. I'm -- I don't recall. I think I'm -- No, I don't know.
- Q. All right. Do you know whether or not Dr.
- 24 Belani has been deposed in this case?
- 25 A. I don't know.

1 O. -- Belani, Reed, Leaper.

- 2 A. Yes.
- Q. All right. Those are studies that you've read in the past.
  - A. Yes.
- 6 Q. All right. And you understand that Dr.
- 7 McGovern has also been deposed in this case?
  - A. I was not aware of that.
    - Q. All right. Have you been provided his
- 10 deposition? I take it "no"?
- 11 A. I don't believe so.
  - Q. All right. Have you been provided the
- 13 deposition of Professor Nachtsheim from the University14 of Minnesota?
- 15 A. Can you spell the name, please?
- 16 Q. I'll try. N-A-C-H-S-H-T-E-I-M, I think.
- 17 He's a professor of statistics.
- 18 A. No, I don't believe so.
  - Q. All right. Have you been provided the
- 20 deposition of Robert Gauthier?
  - A. I don't recall. It's possible, but I -- I
- 22 don't know.
- Q. All right. But in any event, there are a
- 24 number of studies that -- on -- on forced-air warming
- 25 and Bair Huggers that you have read in the past but

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- Q. All right. And you -- you have not been provided with and have no knowledge until now, maybe,
- 3 that Mr. Reed has also been deposed in this case;
- 4 correct?
- 5 A. I don't know.
- 6 Q. All right. Professor Leaper has also been
- 7 deposed in this case. Have you been provided a copy 8 of his deposition?
- 9 A. I -- I don't
  - A. I -- I don't know. I don't think so.
- 10 Q. All right. And they were all -- there were
- 11 several trips over to the United Kingdom to depose
- 12 these study authors with respect to studies that they
- 13 wrote and -- and their methodology and conclusions
- 14 with respect to forced-air warming.

You have not been provided any of those depositions in connection with your work on this case; have you?

- A. I don't believe so.
- 19 Q. And in fact you don't cite them even as
- 20 materials that you've considered, despite the fact
- 21 that you have in fact read them at some point; is that
- 22 fair?

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- A. What do you mean by "them"?
- Q. The studies; Legg, Dasari, --
- 25 A. Okay.

- 1 have not been disclosed as part of the materials
- 2 you've considered on this Exhibit 4; correct?
  - A. Yes.
- 4 Q. And similarly there's no disclosure either
  - in your report or on the Materials Considered of
- 6 articles authored by Kurz or Sessler; correct?
  - A. Yes.
- 8 Q. And do you understand that both Dr. Kurz and
- 9 Dr. Sessler have been deposed in this case as well;
- 10 correct?
- 11 A. I didn't know Kurz had been deposed. I knew
- 12 Sessler had been deposed.
- 13 Q. All right. And have you been provided
- 14 copies of Kurz and Sessler?
  - A. I was provided a copy of Sessler.
- 16 Q. All right. And did you read it?
- 17 A. Yes.
- 18 Q. When?
- 19 A. I don't remember.
- 20 O. But --
- Was that with respect to Walton; do you have any idea?
- A. I -- I can't remember.
- Q. All right. So in any event you've been
- 25 provided a copy of one of the depositions of Dr.

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- Sessler, we don't know which one, and it doesn't 1
- appear anywhere on the Materials Considered on Exhibit
- 3 4: correct?

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- A. No.
- 5 O. Correct?
- 6 A. Yes.
  - Q. Okay. And as you sit here today, you don't
- 8 know why that is.
- A. It's -- It's material I looked at a long
- 10 time ago, and.
- 11 Q. And they didn't -- they didn't merit
- 12 inclusion on the Materials Considered?
- 13 A. I -- It's --
  - As I said, it's a -- it's an omission. I --
- I was focusing on the report, and I -- I was 15
- transmitting to counsel what I was reading at the
- time, and I didn't go back and say, well, these are 17
- 18 all the other things I have read, too.
- Q. Okay. But you did cite, in the Materials 19
- Considered, two orders from Magistrate -- Magistrate 20
- Noel, and also from Judge Ericksen, with respect to 21
- 22 VitaHEAT; is that right?
- 23 A. Which exhibit?
- 24 O. Page 3 of Exhibit 4.
- 25 A. Yes.

1 Q. [Clearing throat.] Excuse me.

Is -- Is the report that you prepared in connection with the MDL shorter or longer than the report that you provided in the Walton matter?

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Page 169

- A. I can't tell.
- 6 Q. You have no recollection as you sit here 7 today?
- 8 A. I didn't count the pages, if that's what 9 you're referring to.
- 10 Q. Okay. And the -- your signature on the MDL report appears on page 15; is that fair? 11
  - A. Yes.
- 13 Q. All right. Towards the top of page 14 of your report you provide an example about the 14
- difference in diameter as between ping-pong balls and 15
- basketballs. Do you -- Do you see where I'm at, where 16
- 17 that is in your report? The first full paragraph on
- 18 the top of page 14?
  - A. Yes. I see it.
- 20 Q. Would you agree that describing a filter as
- high efficient is only meaningful when you know both 21
- 22 the rate and size of the particles that are being
- 23 filtered?
- 24 MS. LEWIS: Objection, form.
- 25 A. Can you repeat the question, please?

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Q. And so referencing legal orders from two of

the judges presiding over this case merited inclusion on the list of materials considered, but it seems a

4 number of articles and depositions that you have been

provided did not make the list. Is that fair?

- A. Well I think in this particular case this was -- excuse me -- this was something that was contemporaneous with writing the report and so I was just basically giving a list of what I looked at, and -- and this appeared relevant because it looks at two different modes of heat transfer.
  - Q. Right. But --

But with respect to decisions about what's relevant and what's not, you're an engineer, right, not a lawyer?

- A. Yes.
- 17 Q. All right. And do you recall how long your 18 report was, the report you prepared in the Walton 19 case?
- 20 A. No.
- Q. Is it about the same length, or is this --22 is the MDL report shorter or longer than the first
- time you wrote a report? 23
- 24 MS. LEWIS: Objection, form.
- 25 A. Please repeat the question.

Q. Yes. I said, would you agree that describing a filter as high efficient is only

3 meaningful when you both -- when you know both the 4 rate and size of the item that is being filtered?

MS. LEWIS: Objection, form.

- 6 A. The -- The "rate" I'm assuming you mean the 7 flow rate.
  - Q. Yes.
  - A. Okay. Yes, you do need to know the flow rate. You do need to know the -- the size. You also need to know the mass, and you also need to know the -- you said the "item," is that -- was that in your question?
    - Q. The size of the thing being filtered.
    - A. Right.
- 16 Q. It could be a particle, it could be 17 something bigger.
  - A. Right.

19 So -- So then you would have to look also at 20 the item and whether the item is agglomerated or can

- be a free particle, a single particle, and so it would 21
- -- you would need to look at what is the -- the -- the 22
- 23 intended purpose of the filter.
- 24 Q. Okay. And without knowing that, it's not a
- 25 -- it's not meaningful to describe a filter as "highly

Page 170 Page 172 efficient." Does that seem fair? mentioned an abstract. 1 1 2 MS. LEWIS: Same objection. 2 O. Never mind. 3 A. Without knowing those parameters we 3 You describe, in what you number as the seventh -- as number 7, starting at the bottom of page 4 discussed? 4 5 5 8 and moving onto page 9, as the sources of dust, heat Q. Yes. 6 A. Well it's also --6 and gas outflows in the operating room. Do you see 7 We usually give numbers for -- for those 7 where that begins? 8 efficiency, so I don't know what you mean by "highly." 8 A. Page 7? 9 Q. Precisely. 9 Q. It's number 7, which begins at the bottom of 10 So saying "highly" efficient on its own is page 8 --10 not something that would be significant to a person 11 11 A. Yes. trying to understand a filter. You need to know the Q. -- of your report. 12 12 flow rate, or the -- or the specific MERV rating, for A. Yes. 13 13 example, because a MERV rating explains the size of 14 Q. Do you see that? 14 A. Yes. the particle and how many of those particles will be 15 15 removed with a particular filter medium; is that Q. And you -- you talk about here a number of 16 16 17 right? 17 different machines that -- or instruments that may be 18 A. I don't understand your question. I'm sources of dust, heat and gas in an operating room. 18 Is that right? 19 sorry. 19 20 Q. Okay. So -- And I want to say it was in Dr. 20 A. Yes. 21 -- one of the Kuehn depositions. There was a -- an 21 Q. So you agree that equipment -analogy made that you could have a -- the screen You would agree that equipment that blows 22 22 around a tennis court is a filter for tennis balls to 23 air can contaminate the sterile field; correct? 23 24 keep them from going to the street. It may be highly 24 MS. LEWIS: Objection, form. efficient to keep tennis balls out of the street, but 25 A. Equipment that blows air by itself --Page 171 Page 173 it may not be highly efficient to keep smaller-sized 1 What was the question, please? Can you golf balls or some other type of particle that could 2 2 repeat it? 3 3 fit through the fence. Q. Equipment that blows air can contaminate the 4 Does that make sense a little bit? You 4 surgical field; correct? 5 following me that far? 5 MS. LEWIS: Same objection. 6 6 A. I didn't read that part, or -- or I -- I'm A. And your question was whether I agree with 7 7 going by what you're saying. that? Q. Okay. So --Q. "Yes" or "no"? 8 8 9 But when you talk about a filter and 9 A. Yeah, well it's not a yes-or-no answer filtration efficiency, like a HEPA -- pardon me -because I think I mention in my report the -- the 10 10 [clearing throat] a HEPA filter. Do you know what a air-handling system blows air into the operating room, 11 11 12 HEPA filter is? 12 13 A. Yes, I know what a HEPA filter is. 13 Q. Yes. 14 Q. Okay. And do you know that a HEPA filter 14 A. -- so. has specific requirements to it, right, is it 99.97 15 Q. But talking about equipment inside the 15 operating room; you would agree that equipment that percent of particulates at .3 microns will be filtered 16 16 blows air can -- can contaminate the sterile field. out when passed through a HEPA filter; correct? 17 17 18 A. Yes. 18 MS. LEWIS: Same objection. Q. All right. But calling a filter "high 19 Q. The surgical field, also the sterile field. 19 20 efficiency" on its own, without knowing the things 20 A. Equipment that blows air that contains described in a HEPA, the size of the particle and the infectious organism, for example, the --21 21 efficiency rate, 99.97 percent, just saying "high 22 22 Q. Doctor, and I don't mean to cut you off. We 23 efficiency," in the abstract, is not going to tell you 23 can get to your --24 anything. Agreed? 24 MS. LEWIS: But you did.

25

A. In which abstract? I'm sorry. You

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MS. ZIMMERMAN: Counsel, you can just wait

Page 174 Page 176 for a minute. 1 Q. You list a CVVH machine as something that 1 2 may blow air; correct? 2 Q. Because this is a yes-or-no question. 3 Can it contaminate it or can it not 3 A. Yes. That's a central venous venous contaminate it? I'm happy to hear your explanation 4 hemodialysis machine, yes. 4 about why it may or may not after you've answered 5 Q. Yes. 5 6 whether it is -- you agree it's possible. 6 You list the OR computers as something that 7 may blow heated air into a operating room; correct? 7 MS. LEWIS: Objection, argumentative on how 8 he's to answer a question. He can answer the 8 question the way he believes he needs to answer the 9 Q. You also list ceiling-hung display monitors 10 as something that may blow air into an operating room; 10 question. 11 MS. ZIMMERMAN: The question calls for a 11 correct? 12 12 A. Yes. yes-no answer. 13 MS. LEWIS: Not necessarily. 13 Q. And you go on on the next page to explain 14 A. It's not amenable to a yes-no answer. that dust inside these kinds of machines can contain 14 Q. All right. So you're not capable of or not bacteria: correct? 15 15 willing to answer it "yes" or "no"? A. Yes. 16 16 17 A. I -- I didn't say I am not capable. I said 17 Q. And all of the machines that you've listed at the bottom of page 8 and the top of page 9, if they 18 it's not --18 blow air they can contaminate the sterile field; Q. No. That's what your counsel said. 19 19 20 A. No. I'm -- I'm saying to you it's not 20 correct? amenable, as the transcript shows, to a yes-or-no 21 MS. LEWIS: Objection, form. 21 22 A. They can contaminate which field? 22 answer. 23 23 O. The sterile field. Q. So your Section 7 in your report talk about 24 a number of different sources of dust, heat and gas in 24 A. If they blow air with infectious organisms, 25 25 an operating room; correct? yes. Page 175 Page 177 A. Yes. 1 Q. Right. 1 2 Q. And you say, in the third sentence: "In 2 And that in -- the sterile field includes 3 some cases, the air blown into the operating room's the surgical site; correct? A. Yes. 4 ambient environment may also contain infectious 4 organisms or droplets from the patient's respiratory 5 5 MS. LEWIS: Same objection. system"; correct? 6 6 Q. And you agree that the Bair Hugger device A. Yes. blows air; correct? 7 7 8 8 Q. So you would agree that air blown in an A. Yes. 9 operating room may contain infectious organisms; 9 Q. Now you go on, towards the bottom of page 9 correct? you talk about multiple sources of heat besides just 10 10 the -- the forced-air warming blanket. Do you see 11 A. Yes. 11 that? It's the last full paragraph on page 9? 12 Q. And you list a number of different devices 12 13 in an operating room that may -- may blow air; 13 A. Oh yes. Umm-hmm. 14 correct? 14 Q. All right. And you -- you provide a number 15 A. Yes. 15 of examples, including high-intensity surgical lights; 16 Q. And you list physiological monitors. That's 16 right? As a source of heat? one; correct? One of the items that you list at the 17 17 A. Yes. 18 bottom of age 8? 18 Q. Also endoscopic lights; right? A. Yes. A. I don't see endoscopic lights in there, but. 19 19 20 Q. You list an anesthesia machine as something 20 O. So it says, "including but not limited to that may blow air; correct? high intensity surgical lights and endoscopic 21 21 lights..." A. Yes. 22 22 23 Q. You list an x-ray machine as something that 23 A. Oh, I must have a different version then, of may blow air; correct? 24 the -- of the report. 24 25 A. Yes. 25 MR. ASSAAD: Mark it.

Page 178 MS. ZIMMERMAN: Well that is marked. 1 Q. What is the airflow rate coming out of the 1 2 blanket when it's attached to a 750 series? 2 MS. LEWIS: No. She's -- You're talking 3 about the [indicating] --3 A. Okay. So it's not at the port. In general, A. Oh. Oh, I'm sorry. 4 the blanket in general. 4 5 MS. LEWIS: -- the next-to-the-last 5 O. Yes, coming out of the blanket, the holes on 6 6 the bottom of the blanket? paragraph. 7 A. It's -- It's the second sentence. I'm 7 A. Assuming there are no leaks, then it would 8 8 be the same, that CFM value that we discussed that the sorry. 9 9 Bair Hugger produces, then that would come out of the Q. Yes. 10 A. I was looking at the later sentences in the 10 blanket. same paragraph. I'm sorry. 11 11 Q. All right. And you know, from reviewing It is there. 12 corporate documents, that there are leaks in the 12 Q. Okay. And then you also note, as -- various 13 13 blanket from time to time? electronic equipment also provides heat to the 14 14 MS. LEWIS: Objection, form. operating room; correct? A. I have not reviewed those documents, if --15 15 if -- if you -- Yeah. I have not -- I'm not aware of A. Yes. 16 16 17 Q. Would you agree that -- that heat can affect 17 reviewing documents that... airflow in an operating room? 18 Q. Do you know what the temperature is coming 18 A. It can, depending on -- on the conditions. out of the -- the upper body blanket when it's 19 19 attached to the Bair Hugger machine, the 750? 20 If there is a -- So it depends on the magnitude of the 20 heat, the temperature difference. 21 A. Yes, I do, but I can't recall. It's lower 21 22 22 O. Sure. than 43. 23 But the answer to my question is "yes"? 23 Q. It's warmer than the patient; right? 24 A. It is possible. 24 A. Yes. Yes. 25 Q. Okay. Do you, by the way, do you know what 25 Q. Okay. Otherwise it would be cooling them; Page 179 the airflow rate is for the Bair Hugger 505? right? 1 1 A. Not off the top of my head, so. 2 2 A. Yeah. 3 3 Q. All right. What about the 750? Q. Okay. What about the pressure, will that 4 A. I can look it up. I think it's... I have a 4 reduce the airflow out of the blanket? 5 number in mind, but I -- I -- I don't want to mention 5 A. The pressure where? Q. Yeah. If there's a -- [clearing throat] 6 it because I don't have the document. 6 7 7 Q. No, that's fine. You don't have to guess. Pardon me. 8 A. I have -- I have read it, I know what it is, 8 If there's a -- When you attach the blanket 9 but I can't recall. 9 is there a resultant pressure drop? Q. Do you know, as you're sitting here today, A. Pressure drop at what location? 10 10 Q. In the force of the air coming out of the what the high temperature setting is for the Bair 11 11 12 Hugger? 12 blanket. 13 A. Yes. 13 A. I'm sorry. I don't understand your Q. What is it? 14 14 question. 15 A. I believe it's 43. Q. So if you're measuring temperature of the 15 Q. Do you know what the other settings are? 16 air coming out of the machine without a blanket 16 17 A. No, I don't remember. attached, you put the blanket on, is that going to 17 18 Q. Okay. Do you know what the airflow rate is 18 impact the temperature coming out of the blanket? coming out of the blanket when it's attached to a 750? A. You -- Your previous question was about 19 19 20 A. The airflow rate in liters per second, or in pressure, so now you're shifting to temperature. I 20 just want to make sure --21 21 Q. Yep, and I will shift back. 22 Q. Sure. 22 23 23 A. Okay. So what is your current question, You usually do cubic feet per minute; right? A. The question was the way it comes out of the 24 please? 24

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blanket?

Q. Measuring the temperature of the air coming

Page 180

Page 181

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Page 182 out of the machine at the end of the hose you may have 1 one measurement; is that correct? 2 3 A. Yes. 3 4 Q. And when you attach the blanket then to that too, is correct. 4 5 hose will the temperature remain the same coming out

A. I have not done that measurement.

of the -- the jets on the bottom of the blanket?

- Q. So you don't know. 8
- 9 A. Yeah.

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- 10 Q. Okay. So the 43-degree setting, is that the temperature that comes out of the machine, or at the 11
- distal end of the -- out of the blower itself or the 12 distal end of the hose? If you know. 13
- A. I -- I don't know which -- which temperature 14 they're referring to, whether it's at the hose or at 15 the -- at the heater unit. 16
- 17 Q. Okay. Do you know how many watts come out of a Bair Hugger? Say the 750. 18
- A. Yeah. I've seen a figure of 500 watts 19 20 mentioned.
- Q. Where did you see that? 21
- A. I can't remember. 22
- 23 Q. Yeah. And did you cite to it in your
- 24 materials?

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25 Yes, I think you do.

A. Because it just has a number, I cannot tell you one way or another. So if you produce the actual document I may be able to tell you whether it's -- it

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Q. Well I can represent to you that one of the 6 questions I had was why were you citing to this, because it doesn't support what --7

- 8 A. Then it's a -- it's a typographical error.
  - O. Okav.
- A. I think this was meant to be "xii," 10

11 Memarzadeh.

- Q. So both "xi" and -- so "xi" and "xii" should both be citing to Memarzadeh?
- A. Correct. I believe so, --
- 15 Q. All right.
- 16 A. -- yes. Without having seen what "7132" 17 refers to.
- 18 Q. I don't have a paper copy of this, but 19 3MBH00007132 [handing laptop to the witness] you can 20 see the Bates label up on the right-hand --
  - A. Umm-hmm.
- 22 Q. -- side.
- I'm sure counsel can --23
- 24 A. Yeah.
- 25 Q. -- verify that's the number.

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- A. Yes.
- 2 Q. You list it in your materials, and then you
- have a citation to "xi," that's a 3M document?
- 4 A. No.
- Q. "No"? 5
- A. No. 6
- 7 Q. What do you cite to?
- A. It's "xii." 8
- 9 Q. Isn't that Memarzadeh?
- 10 A. Yes.
- 11 Q. So that's the study about the forced-air
- 12 warmer being on or off for a zero percent deposition 13 of contaminant sources on the patient.

My question was about 500 watts. So you say, in the sentence before your citation to

Memarzadeh, "there's 500 watts heat dissipation from a 16 forced air warming device," and you cite to "xi." Is 17

that correct? 18 19

- A. Yes. That's what it shows on the report.
- 20 O. Okav.
- 21 A. I'm not sure whether the references got
- 22 crossed, but -- Oh. Yeah. I think the 500 was from
- 23 Memarzadeh.
- Q. Okay. So this "xi" reference at the end is 24
- incorrect? 25

1 A. Yeah.

- 2 Q. This particular document doesn't say 3
  - anything about 500 watts of heat dissipation; does it?
  - A. That's --
  - This is one page?
- 6 Q. Yes.
- 7 A. (Witness reviewing laptop.) No.
- 8 Q. So that citation is another error; correct?
- 9 A. Yes.
  - Q. All right. Assuming that the 500 watts is
- correct for a Bair Hugger device, do you know how many 11
- 12 BTUs that is?
- 13 A. I can make the calculation. I don't have
- 14 the conversion table in front of me. 15 Q. Well you'd agree that you -- that someone
- 16 who's studying the impact of any particular device in the operating room needs to account for the heat 17
- 18 dissipated from the various devices in order to
- understand that impact; correct? 19
- 20 A. Please repeat the question.
- 21 Q. I will try.
- 22 Someone who's studying the impact of a
- 23 particular device in the operating room needs to
- 24 account for the heat dissipated from various devices
- 25 in the operating room in order to understand the

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Page 186

impact of the device on the operating room; correct? 1 2 MS. LEWIS: Objection, form.

A. Yeah. The -- The -- The -- I -- I --Actually I don't fully understand. I'm sorry. It was

a long question.

Q. It was.

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And in fact that's really exactly what you're saying here, right, in the last full paragraph on page 9, there's multiple sources of heat, not just a forced-air warming blanket; right?

A. Yes.

Q. And so if we're going to study the impact that the Bair Hugger has, for example, on the operating room, we need to know what else is in the operating room; correct?

A. Yes.

17 O. And we need to know, of the things in the operating room, which might be sources of heat; 18 19 correct?

20 A. Yes.

Q. And we need to know how much heat each of 21 22 those items may generate; correct?

A. Yes. 23

24 Q. And we need to know all of that in order to 25 have a reliable model of an operating room; correct? 1 Q. So are the -- are the patients losing heat 2 because the operating room is cold, or because --3 because of the redistribution of heat as a result of 4 anesthesia?

A. There are --

There are multiple mechanisms of -- of heat, so anesthesia is one of them. There's also exposure of the internal organs if there is an open incision.

Q. So getting back to you cite to Memarzadeh talking about a computational fluid dynamics model and particle-tracking methodology.

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Page 189

Do you see that part in the last full

paragraph on page 9? 13 14

A. Page 9.

Q. Yes. 15

A. Memarzadeh? 16

17 Q. Yes.

18 A. I don't see that. On page 9?

> Q. So you say: "In one study" -- The last full paragraph on page 9. You're on the right page. The

21 last --

22 A. So the last full paragraph.

23 Q. Yes. "In one study" --

24 A. Yes.

25 Q. -- "employing computational fluid

Page 187

A. Yes. 1

Q. And you'd agree that --

Well we'd also need to know what kind of heat is being absorbed by things in the operating room; correct?

A. Yes.

7 Q. All right. Do you know, as you sit here,

how much heat is absorbed by the arms and chest of a 9 body?

A. When --

You're talking when a Bair Hugger is used, or in general?

Q. Both.

A. In general in an OR I think the --

15 What were the parts of anatomy you ask about? 16

O. The arms and the chest.

18 A. They -- In general they would actually lose 19 heat because the operating room is pretty cold, in general. 20

Q. Okay. 21

A. And in the case of the Bair Hugger, it would

gain -- it would absorb heat and -- and the 23

calculation can be made by knowing the -- the 24

parameters and the temperature -- and the temperature.

dynamics" ---1

A. Yes, umm-hmm.

Q. -- "and particle-tracking methodology, the total heat emission from these sources, as well as the patient, accounted for more than four times the 500 watts heat dissipation from a forced air warming device."

8 You'd agree, to have an appropriate model 9 each of these potential sources of heat needs to be 10 included in the model; correct?

12 Q. With respect to Memarzadeh, did you review 13 the entire study?

A. I believe so.

15 Q. All right. Because there's also a letter to 16 the edit -- a letter to the editor.

A. Yes.

Q. Have you read that?

A. So let me check. (Witness reviewing 19 20 exhibit.) Yes, because that's -- that's what I -- I

-- It's the letter to the editor, Journal of Hospital 21

22 Infection.

23 Q. Right.

> So you cite to the letter to the editor, not to his actual study. Fair?

> > 48 (Pages 186 to 189)

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- A. I also read the study, so I think -- it's -it's a long time ago. I think the 500 was in the -the study.
- Q. Is it your testimony, as you sit here today, that you -- that this citation is to the study itself?
- A. If you put the two documents in front of me I can tell you which one it is. I --
- Q. Well what you cite in "xii" is Memarzadeh, "Active warming systems to maintain perioperative normothermia in hip replacement surgery. Letters to the Editor - Journal of Hospital Infection."

Does that help refresh your recollection as to whether this is a letter to the editor or the actual study itself?

A. Well clearly this is the letter to the editor you had asked me, that is why I went back to the reference to see whether it was the letter to the editor.

What I am saying, sitting here now without having the study and the letter to the editor, I cannot say either way whether the 500 watts came from the letter to the editor or the study.

- Q. Okay. And is it your belief, as you sit here, that you have seen Memarzadeh's study?
- 25 A. Yes.

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2 A. It's -- I -- I don't know off the top of my head, but it's -- it's something I can find, and I -if I recollect, I believe Memarzadeh touched on that 4 5 because when I say it's four times, what I remember 6 doing was I added all the different sources of heat 7 that he had enumerated.

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Page 193

- Q. But you'd agree that the anesthesia equipment may also be generating, it's a source of heat in the operating room; right?
- A. Yes.
- Q. And as you sit here today, do you have any idea how many BTUs per hour the anesthesia equipment would gen -- produce in an operating room?
- 15 A. It's -- It's something that can be measured. I didn't measure it. 16
- 17 Q. All right. And you'd agree --
- 18 A. And I believe Memarzadeh did give that 19 number.
- Q. Okay. 20
  - A. But I'm going from memory. I may be wrong.
- 22 O. All right. And you'd agree that the LCD
- monitors that are typically in an operating room are 23
- also a potential source of heat; correct? 24
- 25 A. Yes.

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- Q. But it's not cited on Exhibit 4 or at the 1 end of your report either; is it?
- A. (Witness reviewing exhibits.) No. 3
- Q. Do you know whether or not Dr. Memarzadeh's 4 5 study is published or unpublished?
- 6 A. I don't know.
- 7 Q. Do you know how many -- Do you know how many 8

9 Well you talked about you could calculate the number of BTUs from a Bair Hugger assuming it was 10 500 watts; is that right? 11

- A. Yes.
- 13 Q. Do you know how many BTUs a patient in an operating room may generate? 14
- A. Not off -- Not off the top of my head. 15 16 That's easily available.

- Q. All right. Would 160 BTUs an hour sound 17 18 like an appropriate approximation? If you know.
- A. I don't know. I would have to look at, you 19 20 know -- I usually don't work with BTUs.
- Q. Okay. Do you know how many BTUs an hour a 21 22 surgical team might generate? Assume a surgical team 23 of four.
- 24 A. I don't know, but I can find out.
  - Q. Do you know how many BTUs the surgical

1 Q. And as you sit here, you don't have any idea how much heat they're generating per hour; do you?

A. I've -- I -- I cannot put a number to it as I'm sitting here, but I can find out, and I -- I know they generate heat because I've worked with them.

- Q. All right. And the same can be said for surgical lights and overhead lighting, that they are -- both surgical lights and overhead lighting are sources of heat in an operating room. You'd agree with that?
  - A. Yes.
- 12 Q. All right. And, as you sit here today, you 13 -- I presume you don't know how many watts or BTUs the surgical lights or the overhead lights contribute to 14 the operating room per hour; do you? 15

A. Again, this is -- this is knowledge that I can acquire -- not "acquire." I already have it, but I don't remember off the top of my head. So it is -a lot of it is in the Memarzadeh study.

Q. Okay. And Memarzadeh is in fact the only citation that you provide with respect to heat -- heat dissipated in the operating room; right? There's the cite number "xi," which was an error, and then cite number "xii" is to Memarzadeh's letter to the editor; correct?

Confidential - Subject to Protective Order Page 194 Page 196 A. Yes. 1 A. Where appropriate, yes. 1 Q. Okay. And you'd agree that turbulence is 2 Q. Is it your testimony that the information 2 about heat generated and dissipated is in -- is 3 going to have an impact on particle flow; correct? included as part of the letter to the editor cited at 4 A. Yes. 5 number "xii"? 5 Q. And because of turbulence, particles are not 6 A. Without looking at the letter to the editor 6 going to follow airstreams; correct? 7 I cannot make any statement. 7 MS. LEWIS: Objection, form. 8 8 A. What do you mean by "airstreams"? Q. Okay. 9 A. I'm sorry. 9 Q. Do you understand what airstreams are? 10 Q. But at any rate, you'd agreed that it's 10 A. Yes. important to know all the different heat sources to 11 11 Q. All right. understand their respective impact on the operating 12 12 A. But I want to understand in what context room; correct? you're asking the question. 13 13 A. Yes. Some heat sources may be 14 Q. In a turbulent flow environment, are 14 insignificant, and if that's determined to be the case particles going to follow airstreams? 15 15 then they could be considered negligible and not MS. LEWIS: Objection, form. 16 16 17 factored in, and --17 A. It depends on the size of the particles, the 18 Q. But you'd agree that it's important to know 18 weight of the particles, the shape of the particles. the objective quantifiable amount of heat generated in Q. And why would the size matter, --19 19 20 order to decide whether it's negligible or not. Fair? 20 A. Well --A. Yes. And it also depends on the location, 21 Q. -- if you know? 21 A. -- to take an extreme, if I have a -- a 22 22 yes. really big particle, and that's heavy and that's -- it 23 23 O. Right. 24 And all of that is something that is 24 sticks to something, it may not follow the airstream. objectively measurable; correct? 25 Q. And in any event, you're not going to be 25 Page 195 Page 197 1 offering testimony about particle flow in this case; A. Yes. 1 2 Q. All right. Now you'd agree that no 2 are you? 3 operating room has true laminar flow; correct? A. Could you explain to me what you mean by 4 4

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A. Yes.

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Q. And so you'd agree that when you model airflow in an operating room, turbulence must be considered; correct?

A. Can you repeat the question, please?

Q. Yes.

So you'd agree when -- when airflow inside of an operating room is modeled, turbulence must be considered; correct?

A. If in -- in -- in the model that's being considered there is known to be turbulence, yes.

Q. And you'd agree that all operating rooms are going to be turbulent flows; correct?

A. There are some operating rooms that are described as laminar flow, but they may not live up to that description.

Q. And you agree and understand as a mechanical 20 engineer that true laminar flow is just not possible in an operating room; correct?

A. It is very difficult.

Q. All right. And because of that, turbulence must be considered: fair?

"particle flow"?

Q. You have not --

Well you don't have any -- and I'll search to be sure -- you have not offered any opinions in your expert report about particle movement, and you've done no independent testing or calculations on your own with respect to this case; correct?

A. I -- I did a few calculations regarding the -- the soot, if you consider soot as a particle, and I believe it is considered a particle. I did some calculations there.

Q. All right. So the calculations that you might offer with respect to particles are limited to the section beginning at page 13, number 11; is that right? "Fire in the Bair Hugger"?

A. Yes.

Q. And other than that you are not going to be offering any testimony about particle movement in this 21 22 case: correct?

23 A. As long as particle movement doesn't include 24 the filtration aspects. So I don't know what you mean by "particle movement." Does that also encompass how

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Page 198

the particle moves through the filter, --1 2

Q. All right.

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3 A. -- or -- or more -- more exactly, how it does not move through the filter. 4

O. Well the questions that you are being posed -- or that I was posing to you had to do with modeling particle movement in turbulent airflow. You're not going to be providing expert testimony about that, given your report.

10 A. No, not -- not -- not that I can think of 11 now.

12 Q. Have you --

> Have you been in an operating room when a Bair Hugger is used?

A. Multiple times.

Q. All right. And where have you been in the 16 17 operating room during those operations?

A. Mostly on the anesthesia side, but sometimes on the surgical side.

20 Q. All right.

A. Sometimes I was there actually teaching 21

residents, and then sometimes I -- in one case I had 22 to remind the resident to turn it on. 23

24

Q. Turn the Bair Hugger on?

25 A. Yeah.

Q. All right. Do you know, as you sit here 1

> today, whether Dr. Memarzadeh used RANS or LES in his 2 3

Page 200

Page 201

model? 4 A. I don't recall.

> Q. Do you know what the difference is between the two?

7 A. Superficially. I saw that in the Elghobashi 8 report, and -- and in the Elghobashi deposition.

Q. All right. And -- And what is your

understanding of the difference between RANS and LES? 10

A. Well they are two different methodolo -methodologies, and... So as I said, it's superficial, and there was the -- you know, I -- I don't -- what I mean by that is I don't present myself as an expert in computational fluid dynamics.

Q. Okay. And you would defer to an expert in computational fluid dynamics to explain the difference between RANS and LES and when one approach is better than another. Fair?

20 A. Yes.

(Discussion off the stenographic record.)

22 (Recess taken from 1:47 to 1:54 p.m.)

23 BY MS. ZIMMERMAN:

24 Q. Doctor, you've spent most of, if not all of your professional life working on issues involving

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engineering and science; is that correct? 1 2 A. Engineering and science as it relates to

3 medicine. 4 Q. Okay. And in connection with your -- your

work and dedication to engineering, science and 6 medicine, do you believe in the theory of relativity?

A. You mean Einstein's?

8 Q. Yeah.

A. I mean, that's a -- that's a proven theory.

Q. All right. Do you believe in the theory of 10 11 evolution?

12 Big questions after lunch; right?

13 A. Yeah. You mean personally, or?

14 Q. As a scientist.

A. Yes.

16 Q. Do you believe in the big bang theory?

A. I'm -- I'm not an astrophysicist, so I would 17 18 say I don't know enough to -- to say one way or

19 another.

20 Q. Do you believe in the kinetic theory of 21 gases?

A. Yes. 22

23 Q. Do you believe in collision theory?

24 A. When you say "collision theory," is there a 25 specific theory you're talking about, and similarly to

Q. All right. Is that something that the

resident typically does, or the nurse, or who, if you 2 3 know? A. Actually, thank you for making that

5 correction. That was not a resident, that was a nurse. A Certified Registered Nurse Anesthetist, to 6

7 be exact. Nurses don't -- don't do anesthesia. CRNA. 8

Q. Yes.

9 Do you know Dr. Memarzadeh, by the way? 10

Q. And you've looked at the letter to the 11 12 editor at least; right?

13 A. Yes.

14 Q. And -- And you --

15 A. Actually I looked at the study, too.

Q. You looked at the study, too, even though 16 it's not on Exhibit 4. 17

18 A. Yes.

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19 Q. And so you're aware, then, from looking at -- at his study, that -- that even Dr. Memarzadeh 20

found that the 505 disrupted the airflow in the 21 operating room; correct? 22

MS. LEWIS: Objection, form.

24 A. I -- I don't -- I don't recall that, and it's been a long time since I -- I read it.

Confidential - Subject to Protective Order Page 202 Page 204 heat, what is the type of heat. There are many -the previous question? 1 2 Q. Well you agree that excess heat in the 2 O. Do you --3 I've got just kind of a line of things, and 3 operating room --MS. LEWIS: He didn't finish, Genevieve. 4 if you've got a sense about your reaction, I'm happy 4 5 to hear them, but I'm not going to get into a big 5 MS. ZIMMERMAN: I know. 6 scientific debate about what each of these is. 6 MS. LEWIS: He didn't even finish his 7 7 Do you believe in climate change theory? sentence. 8 A. I personally believe in it, but I know there 8 MS. ZIMMERMAN: We're having paragraph upon 9 are people who don't. 9 paragraph, and it's educational, but we have limited 10 Q. But you'd agree that the vast majority of 10 time here. scientists believe in climate change theory? 11 MS. LEWIS: I understand, but in fairness 11 A. I have not talked to the majority of 12 to Dr. Lampotang, you asked him a question but you 12 won't let him finish his answer. You broke him off 13 scientists, I have not done a poll, so I can't answer 13 your question. 14 in sentence. 14 Q. Okay. So you doubt that a majority of 15 15 O. Doctor, -scientists believe in climate change? 16 MS. LEWIS: Were you finished with your 16 17 A. I don't have data to make -- to either doubt 17 answer? or not doubt. I have not read a publication that says 18 A. Yeah, so you really have to look at all 18 19 these factors before you can answer that question. we polled these scientists, so. 19 20 Q. All right. Do you understand the basic laws 20 O. I understand that. 21 of thermodynamics? 21 And to the extent that your counsel wants to 22 ask you for additional confirmation or explanation 22 A. Yes. 23 Q. Do you agree with the conservation of 23 about any of these questions, she's free to do so. 24 energy? 24 But my question to you was about whether or 25 A. Yes. 25 not excess heat is going to have an impact or an Page 203 Page 205 Q. You agree that hot air rises. effect on an operating room, which is what I was 1 1 2 A. In -- In certain circumstances, yes. 2 trying to clarify. 3 3 MS. LEWIS: Same objection. Q. And that's really because colder air is 4 denser and sinks, is that right, pushing the warm air 4 A. Yeah, it may in certain conditions, and it 5 up? 5 may not in other conditions. O. And that's based on the first law of 6 6 A. Right. But the -- the hot air may not rise thermodynamics; correct? if there is enough of a counter-current flow 7 7 8 suppressing it. 8 A. What is "that," when you say "that"? 9 Q. Okay. You'd agree with me, though, that 9 Q. Do you think that the Bair Hugger is going excess heat is going to have some effect on the 10 10 environment; right? the surgical table in an operating room? 11 11 12 MS. LEWIS: Objection, form. 12 MS. LEWIS: Objection, form. 13 Q. The extent of the effect is not my question, 13 A. Do I believe that the Bair Hugger will -just the fact that there will be some effect. I'm trying to remember your question -- increase the 14 14 15 MS. LEWIS: Same objection. 15 temperature? 16 16

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- A. What -- What kind of effect are you -- do you have in mind when you say "effect"?
- Q. I don't have a type of effect in mind, just excess heat will have some effect on the environment; agreed?

MS. LEWIS: Objection, form.

- A. It may or may not. It depends on what the 23 environment is, what is the effect, and --
  - Q. You --

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25 A. -- what is the ampli -- the magnitude of the

- to have an effect on increasing the temperature around
  - Q. Have an effect on increasing the temperature around the surgical table.

18 MS. LEWIS: Same objection.

A. When you say "around," do you mean -- where 19 20

What does "around" mean, the surgical table?

- Q. I don't know how to ask that question more 22 23 plainly. 24
  - A. Well it may not, for example, at the foot of the surgical table. That's why I'm trying to

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1 understand what "around" -- what you mean by "around."

Q. So yes, but? If there are parts around the table you think it won't effect, then you can qualify that answer.

But I want to know "yes" or "no," do you think the Bair Hugger has an effect on increasing the temperature around the surgical table when it's on?

MS. LEWIS: Objection, form.

- 9 A. It may or may not depending on where you are 10 measuring around the surgical table.
- Q. How about around the surgeons?MS. LEWIS: Same objection.
- A. It may or may not have an effect depending on what is the condition, whether there is -- the way the system is draped. There are many, many factors.
- 16 Q. There are many factors.
- 17 A. It may or may not.
- 18 Q. All right. And you agree that when the Bair 19 Hugger is turned on, it is generating heat; correct?
- 20 A. Yes.

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- Q. Do you believe, because of the generated
- heat, that the Bair Hugger has an effect on increasing the temperature anywhere around the surgical table?
- 24 MS. LEWIS: Objection, form.
- A. Yes, it may -- it may increase the

1 suppressed.

Q. So the answer, though, is "yes." It -- The effect may be suppressed if there are sufficient downward forces, but if there's heat around the surgical table then you're going to have buoyant forces; correct?

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MS. LEWIS: Object to form, it's already asked and answered.

Do you wish to stick with your previous answer?

A. Yeah, I've al --

MS. ZIMMERMAN: You can stop coaching the witness now, counsel. The answer -- The question was not answered.

MS. LEWIS: He has answered.

MS. ZIMMERMAN: The question was not answered.

18 BY MS. ZIMMERMAN:

- 19 Q. Would you like me to read the question 20 again?
- A. Please.
- Q. If the Bair Hugger increases heat around the surgical table you're going to have buoyant forces;
- 24 correct?25 M

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MS. LEWIS: And you know that's been

Page 207

temperature in some areas of the surgical table.

Q. Okay. And you would agree, if that's true, that the Bair Hugger then also has an effect on the airflow around the surgical table; correct?

MS. LEWIS: Same objection.

- A. Not -- Not necessarily. Again it depends on what is the airflow in that area.
  - Q. So it depends; maybe yes, maybe no.
- A. If there is a -- a big downdraft coming from the air-handling system, then there may -- that heat may not translate into a disruption of the airflow.
- Q. If the Bair Hugger increases heat around the surgical table you're going to have buoyant forces; correct?

MS. LEWIS: Objection, form.

- A. If you agree to the -- to -- that it's going to -- I already explained that it's not necessarily. So if -- if I agree to your "if," then what was your question?
- Q. If the Bair Hugger increases heat around the surgical table you're going to have buoyant forces; correct?

MS. LEWIS: Same objection.

A. I think it's the same answer. If you have enough of a downdraft coming in, it will get

1 answered, so object to the form as asked and 2 answered.

- A. It would depend on what is the ambient temperature, too.
  - Q. It might be sligh -- pardon me -- slight, but there will be an effect; correct?
  - A. No, because let's say the ambient air happens to be warmer than that plume or the heat that's coming out, then you won't get a -- an upward, because what's coming out will be actually cooler than the ambient environment. So there -- there are a lot of other factors to consider.
  - Q. But we're talking about in an operating room, correct, so the air coming out of the Bair Hugger is going to be warmer than the air in the operating room; correct?
    - A. That is correct.
  - Q. And if that weren't true the air coming out of the Bair Hugger would in fact be cooling the patient, not warming the patient; correct?
- A. Well it would depend on what the temperature of the patient is, and the temperature of the -- of
- 23 the air. So if what's coming out of the Bair Hugger
- 24 is warmer than the temperature of the patient, yes,
- 25 the patient will get warm.

53 (Pages 206 to 209)

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Page 210

Q. And that's always the case with respect to setting the Bair Hugger on heat; correct? Forty --

Do you know what the other settings are besides 43?

- A. Well I would say that's not always true. If a patient has malignant hyperthermia, the temperature of the patient may be actually higher than what --
- Q. If a patient has malignant hypothermia, are -- hyperthermia, are they being operated upon?
- 10 A. Yes. That's what -- That's the trigger for malignant hyperthermia. 11
- Q. And they're -- they're having a total hip 12 replacement in that instance. 13
  - A. Yes, that's possible, because the trigger is the volatile anesthetic agent like isoflurane, desflurane.
- 17 O. It's the what?
- A. It's -- It's the trigger for malignant 18 hyperthermia is volatile anesthetic agents, and 19 20 it's -- the malignant hyperthermia is the patient essentially --21
- O. And you're saying "hyperthermia," or hyp --22
- 23 A. Hyper, P-E-R --
- 24 Q. Yes.

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25 A. -- thermia. hyperthermia, and you are asking me whether the

- blanket always transfers heat to the patient, and I'm
- 3 telling you there is an exception where if the patient
- is warmer than the blanket, the air coming out of the 4 5 blanket, then there would not --
- 6 Q. Then they would be getting cooled, if the --
  - A. So yes. Yes.
- 8 Q. -- patient is warmer.
  - Exactly.
- 10 A. Yeah.
  - Q. And that's not typically the case. This is a forced-air warming device typically used to warm the patient; correct?
    - A. Correct.
- 15 Q. All right. I mean, if we brought a Bair Hugger device into this room with us right now and 16 17 turned it on it would further increase the temperature 18 in this room. Do you agree with me about that?
- A. That is true, but that would also be true of 19 other kind of equipment, too. 20
- 21 Q. I think we're about four pages past the 22 question I actually asked.

23 If the Bair Hugger increases heat around the 24 surgical table you are going to have buoyant forces; 25 correct?

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Page 212

- Q. Okay.
- A. I'm sorry.

And the patient develops a very, very high fever very quickly, and if you don't resolve it quickly, very often the patient dies on the table because they basically, to put it in layman's term, burn up.

Q. So I understand that there are many variations on terrible outcomes or unusual circumstances, but we're talking about a normal, standard operation. And I think that you know from your work on this case that the allegations here are focused on total hip and total knee arthroplasties. Now most of those patients are not going to be hyperthermic. Do you agree?

- A. I don't agree.
- Q. You don't agree that they're --

You think most of the patients are hyperthermic.

A. No. I'm sorry.

I don't understand in what context you're saying hyperthermic. What I'm saying is there is a possibility that one of those patients -- so the fact that they're -- whatever surgical procedure they are doing is irrelevant to their risk for malignant

MS. LEWIS: Objection, form.

2 A. I believe I already answered. I said it is 3 possible, but in some -- in some instances you may not get -- because I'm assuming what you mean by "buoyant 4 force" is the air will rise. 5

- O. Yes. And there may be some instances where other parts of the environment work to counteract those buoyant forces. Fair?
  - A. That's correct.
- 10 Q. Okay. I want to turn to the very first opinion that you offer on page 3 in your report. You 11 12 say that: "The Bair Hugger is a forced air warming device, it is a reasonable, safe, easy to 13 14 use...efficacious device."

15 What is the basis for your opinion that it 16 is a safe device for use in orthopedic implant 17 surgery?

- 18 A. There has been no case that I'm aware of where the Bair Hugger has been directly linked as a 19 20 cause of an infection.
- 21 Q. And that's the basis for your assertion that 22 it's safe?
- 23 A. That's one. The -- The filter is effective 24 in addressing capture of the organisms that are 25 relevant to infection.

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Page 215

Q. Any other --1

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Any other basis for your claim that this machine is safe for use in orthopedic implant surgery?

- A. Yes. Because when you have a -- a new device you look -- initially you do your Phase I, Phase II, Phase III clinical trials.
- O. You understand there were no clinical trials in this; correct?
- A. Well I was trying to explain another basis for saying it's safe.

And then after the clinical trials are over you get into what's called post-market surveillance where we look at how does this product, after the clinical trials, so you're right, behave when used over time. And the Bair Hugger has a long track record of being safe. There were -- There is that incident with Moon where there was a fire.

- Q. So I'm going to -- I'm going to stop you there because to the extent that you have started your answer by saying anything about clinical trials, you do understand there were no clinical trials with respect to the Bair Hugger; correct?
  - A. I don't -- I don't --I don't recall one way or another.
- Q. All right.

Q. And you've seen the hand-drawn schematics 1 2 for the -- this product manufactured before the start 3 of World War II?

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Page 217

- A. I don't recall that.
- 5 O. Okay. And do you know, then, that -- that 6 the original 200 series of the Bair Hugger was not for 7 use in an operating room?
  - A. I recall seeing that, yes.
  - Q. And similarly do you recall, or have you been provided by counsel, previous warnings about the risk of airborne contamination in connection with the use of the 200 series Bair Hugger?
    - A. Can you repeat your question, please?
    - Q. I'll try.

Have you been provided by counsel, or found during your own independent research, the warnings contained on the Bair Hugger 200 series?

- A. I don't recall.
- Q. All right. So you don't know that that 19 20 device was specifically warned not to be used in an 21 operating room?
- 22 A. I don't recall.
- 23 Q. All right. And you don't, as you sit here 24 today, don't recall that there was a warning about the risk of airborne contamination in certain instances on

- A. I mentioned clinical trials as an example to 1 set up the post-surveillance context. 2
- Q. Well you -- you do say, in your -- in your 3 report, that you reviewed the regulatory submissions; 4 5 right?

Oh, that's in the "materials considered" on 6 Exhibit 4. You reviewed the design history file, 7 correct, for the 505?

- 9 A. Yes.
  - Q. And also for the 750; right?
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- 12 Q. And also for the -- the 750 redesign history 13 file; right?
- 14 A. Yes.
- 15 Q. So you know, then, from reviewing these documents, that -- that this Bair Hugger was a -- was 16 cleared for marketing through what's called the 17
- 18 Premarket Approval process in the FDA. You know that?
  - A. Yes, that's right.
- 20 Q. And you know then that the -- the predicate product, the pre-1976 Food and Drug Cosmetic Act 21
- Amendment that Bair Hugger relates to is the Sweetland 22
- Bed Warmer manufactured beginning in 1937 to warm 23 24 surgical or hospital beds and to dry casts; right?
- A. I recall seeing something like that, yes. 25

- that -- on that device?
  - A. Was that the --
  - MS. LEWIS: Objection, form.
- 4 A. Was that the exact word for the warning? 5
  - (Lampotang Exhibit 7 marked for
- 6 identification.)
- 7 BY MS. ZIMMERMAN:
- 8 Q. I'll represent to you that this is a
- photograph of the outside of the 200 series of the
- Bair Hugger, and you'll see at the bottom it says: 10
- "CAUTION: THIS MACHINE NOT INTENDED FOR USE IN TH 11
- OPERATING ROOM."
- 13 Do you see that?
- 14 A. Yes.

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- 15 Q. And is this the first time that you've seen
- any of the labels for the 200 series? 16
  - A. I can't -- I --
- 18 I don't know. I could have seen it before
- 19 when I was in the operating room years ago.
- 20 Q. All right. Well hopefully you wouldn't have
- 21 seen this one in the operating room, right, since it
- 22 says not for -- intended -- not intended for use in
- 23 the operating room?
- 24 A. The -- The environment has changed a lot,
- clinical environment.

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Q. And I appreciate that that's true, doctor, 1 2 but I don't have a question pending about how the 3 environment has changed. I just asked if --

You haven't seen --

- A. What I'm trying to say in response to your question, it's not -- because it says it's not intended for use in the operating room that it implies I would never have seen it.
  - Q. Okay.
- 10 A. It is possible people were doing it off label, especially at an academic health center. 11
  - Q. And at any rate, because you've seen the -you've seen the -- the documents with respect to the design history file, you've seen some of the warnings about the 750 -- the 750 and 505; correct?
- 16 A. Yes.

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- 17 O. All right. And you know that those -- those machines are used in an operating room; correct? 18
- 20 Q. But also that they relate back and they used this 200 series product as the predicate product. You 21 22 understand that?
- 23 A. That's likely. I don't have direct
- 24 knowledge of it, but that would seem to be the likely 25 path.

have seen the warnings contained on the 200 series 1 machine: is that fair? 2

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- A. Yeah. I cannot remember whether I did or did not.
- Q. All right. So you don't have any specific memory of warning number 5, the possibility of airborne contamination should be considered if patients with infected wounds are treated with the Bair Hugger? Is that the first time you've heard that before?
  - MS. LEWIS: Objection, form.
  - A. I -- I can't recall.
  - Q. All right. Does that impact --

Well let me ask you this: Does it seem fair that the possibility of airborne contamination must be known if it's warned about?

MS. LEWIS: Objection, form.

- 18 Q. You can't warn about something you don't 19 know about; right?
- 20 A. Well when you say "known," do you mean that 21 it happened, or do you mean that it's a -- it's a --
- 22 it's a possibility, --
- 23 O. It's a known --24
  - A. -- however remote?
- 25 Q. It's a known possibility, which is why it's

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- 1 Q. And as you were evaluating materials provided to you to offer commentary about the
- appropriateness of the warnings contained, did you see
- warnings for the 700 ser -- the 700 and 750 series 4
- 5 Bair Hugger?
- 6 A. Yes.
- 7 Q. All right. Did you see the warnings for the 8 505?
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- Q. And were you provided with copies of the warnings that were contained on the outside of the 200 series?
  - A. I don't remember.
- Q. All right. So you haven't -- at least at 14 this point you don't remember whether or not you saw a 15 warning about the possibility of airborne 16 contamination, that it should be considered if 17 patients with infected wounds are treated with the 18

MS. LEWIS: Objection, form.

- A. That was a long question. Could you please 21 22 repeat it? 23
  - Q. Right.

Bair Hugger?

24 You, as you sit here today, have no memory one way or the other about whether you were -- you 1 on the warning.

MS. LEWIS: Same objection.

- A. Well I think sometimes the warnings are provided as -- as a safety mechanism to -- to be on the safe side.
- Q. And in fact doctors and healthcare providers rely on product manufacturers to provide appropriate warnings about the use of drugs and devices; correct?
  - A. The question again, please?
- O. I said: And in fact doctors and healthcare providers rely on product manufacturers to provide appropriate warnings about the use of drugs and medical devices; correct?
- A. They do, and sometimes they overrule them, but ves.
- Q. All right. And that's because safety is important; right?
- 18 A. Safety is important, efficacy is also important, and sometimes -- I've seen a lot of things, 19 20 like the manufacturers say you should not modify it, I see my colleagues modify equipment all the time 21 22 because --
- 23 Q. And I understand, doctor. There -- You 24 probably see a lot in supervising and interacting with 25 various healthcare providers, but the question is

Page 222 Page 224 about the warnings that you have seen and been 1 A. One of the ways is to warm the fluids that 1 provided by counsel, and how those may potentially 2 2 are administered to the patient. impact the opinions that you have offered in this case 3 Q. So fluid warmer? about known risks associated with this product and the 4 A. A fluid warmer. 5 5 O. All right. What else? adequacy of warnings. Do you have any basis to support your 6 6 A. There's also conductive devices. 7 statement that Bair Hugger is efficacious to reduce 7 Q. And do you have any examples of those? 8 periprosthetic joint infection? 8 A. I believe the VitaHEAT is one. 9 A. Did I write this in the -- I -- I --9 Q. Do you know of any others? 10 Did I write these words verbatim? 10 A. The HotDog. Q. Do you know of any others? 11 Q. Well the issues in this case are about use 11 of this particular product in orthopedic surgery; A. It's possible. I -- I can't recall just 12 12 sitting here. 13 right? 13 A. Yes. 14 Q. All right. So we have fluid warmers, 14 Q. Okay. And --15 conductive warmers; what else? 15 A. Oh, you're talking of normothermia. A. You have forced-air warmers. 16 16 17 Q. No. 17 O. Convective? 18 A. Okay. I'm sorry. 18 A. Convective. Q. Not just normothermia. 19 19 Q. One forced-air warmer is the Bair Hugger; 20 I'm asking, and the question was 20 right? 21 specifically: "Do you have any basis to support your 21 A. Yes. statement that Bair Hugger is efficacious to reduce 22 22 O. Do you know of any others? periprosthetic joint infection?" A. Yes. There is a WarmTouch. 23 23 24 A. The -- The Kurz study is one of them. 24 Q. All right. Anything else? 25 Q. So that's one of the -- that's one of your 25 A. Yeah, it's -- I believe the Mistral is one, Page 223 Page 225 1 but I can't -- I can't remember. There is -- I 1 believe it is, so. And another technique is to warm 2 That's something that you rely on for that 2 3 statement? blankets in an oven --4 4 A. Yes. Q. Okay. 5 Q. But of course that's not cited in your 5 A. -- and put the warm blankets over the 6 6 paper. patient. 7 A. I am sorry if it's not. 7 Q. And what about pre-warming the patient; can 8 Q. Anything else? you do that with any or all of these modalities? 9 A. Sitting here, I can't recall. I'm sorry. 9 A. I don't think you would give heated fluids Q. All right. Turning to the second --10 10 preoperatively. Turning the page, I guess, it's a Q. Okay. Do you know whether or not, for 11 11 12 continuation of your first opinion, top of page 4. 12 example, warmed blankets, blankets warmed in an oven You cite to the Center for Disease Control updated 13 13 or something to that effect, are those used for guidelines, and talk about the importance of preoperative warming? 14 14 maintaining normothermia. 15 15 A. Yes. 16 Does the CDC make a recommendation one way 16 Q. All right. Are convective technologies also or another about whether normothermia must be achieved 17 used for preoperative warming? 17 18 through preoperative or intraoperative warming? 18 A. Yes. A. In this document, or in general? 19 Q. All right. Are conductive technologies also 19 20 Q. In the document that you cited to. 20 used for preoperative warming? 21 A. I believe they didn't specify the route, the A. I'm not aware of it. It's possible. 21 Q. Okay. So the only one that you think maybe 22 method. 22 23 23 isn't used preoperatively is the fluid warmer; is that Q. All right. And while we're talking about 24 that, what are the methods for maintaining 24 right? 25 normothermia? A. Correct. Yeah.

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Q. Okay. And from an anesthesia -- an anesthesia perspective, would you agree that it doesn't matter which modality is used to achieve normothermia so long as normo -- normothermia is achieved?

MS. LEWIS: Objection, form.

A. From an anesthesia modality?

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Q. From an anesthesia perspective, would you agree it doesn't matter which modality is used to achieve normothermia so long as normothermia is achieved?

MS. LEWIS: Same objection.

- A. There is an element of time involved. So if you achieve normothermia, but towards the end of the case and the patient has been shivering, that would not be a good situation. So you do want to have a rapid transient phase where you achieve normothermia 17 and reach a, as fast possible, steady state in -- in patient temperature.
- Q. All right. But you're not, sitting here today or in your work at a hospital, advocating for -for a particular brand of patient warming, you care about the patient being normothermic. Is that fair?
- A. Within -- Within the parameters of the clinical environment, so in our University, and that's

Q. The last sentence of this first section you say: "Other warming modalities may have risks not present in forced-air warming."

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What risks do you believe are present in forced-air warming?

MS. LEWIS: Objection, form.

- A. One risk in forced-air warming, and I believe that's been documented, the -- it was used without the blanket.
  - Q. Hosing?
- A. Yes. 11
  - Q. Anything else?
  - A. I mean, if you had a -- a runaway -- a bad thermostat or thermocouple you could end up with air, conceivably, that could do some -- some burns to the
  - Q. Right. And you're aware that that has in fact been an issue with respect to Bair Huggers; correct? Are you aware of that?
- 20 A. Not specifically to the Bair Hugger. It's 21 been awhile since I read that.
  - Q. Okay. At any rate, are you aware of any other risks associated with the use of forced-air warming? You mentioned the practice of hosing. Is that a risk because of potential contamination in the

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- what I'm experienced with, we use the Bair Hugger. And a lot of our cases now are getting shorter and shorter, and -- and being able to get to normothermia quickly is -- is clinically relevant and indicated.
- Q. All right. And in preparing for this case or perhaps in your practice, are you aware that there are studies that say that forced-air warming is not effective for the first hour?
- 9 A. I believe I've seen something like that, 10 ves.
  - Q. Okay.
  - A. I've also seen other studies that say it's -- it's quicker to get the patient to normothermia than other methods.
- 15 Q. Would you agree that normothermia and the study of normothermia has been essentially Dr. 16 Sessler's life work? 17
  - A. He's done a lot of publication in that field, yes.
- 20 Q. And publication and independent research as 21 well; correct?
  - A. Yes.
- 23 Q. And you believe he's an expert on issues 24 related to normothermia?
  - A. Yes.

1 machine?

- 2 A. Well I think the -- it's a jet of air 3 instead of a diffused, and so you get a lot of 4 localized heating.
  - Q. What is your understanding of what the practice of hosing entails?
- A. You put the hose below a regular surgical 7 8 drape and direct it to the patient.
  - Q. Instead of attaching it to the blanket?
  - A. Yes.
- Q. Okay. And so then that is -- the danger 11 12 posed there has to do with a stronger jet of air?
- 13 A. A localized heating instead of a diffuse 14
  - Q. All right. And so your -- your understanding of the risk of this hosing has to do with localized heating, not because there's a greater airstream.
- 19 A. Well the -- the heat transfer is going to be 20 related to the flow rate.
- Q. Yeah. 21
- 22 A. And the other risk of using the hosing,
- 23 according to, for example, Avidan, is that the blanket acts as an additional filter should the hose have been 24
- - contaminated, for example, through the clinician

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touching the side of the hose with contaminated hands. 1

- Q. Okay. So setting aside Avidan for a minute, the risks that you believe to be associated with forced-air warming have to do with this hosing practice because of localized heating and heat transfer issues, and anything else? It's just hosing.
  - A. Hosing and --

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- Q. And a broken thermocouple where they might get burned.
  - A. Yeah, and not using a blanket, yeah.
- Q. All right. No other risks that you're aware 11 of with respect to forced-air warming. 12
- A. I have seen studies that have used surrogates to -- to allege that there is a risk. 14
- Q. A risk of what? 15
- A. In some cases infection, and -- but there 16 17 has been no documentation of a actual patient getting infected compared to, for example, the burns. 18
  - Q. So you are aware that there are some studies that -- that raise the issue as to whether or not a forced-air warming system may increase infection risk. Is that a fair characterization?
- 22 23 MS. LEWIS: Objection, form.
- 24 A. There are --

There are some studies that use surrogates

1 last sentence.

- A. Yes.
- Q. So in order to -- to conclude "other warming modalities may have risks not present in forced-air warming," you'd agree with me you need to know what the risks are that are associated with forced-air
- 7 warming. Fair? 8
  - A. Yes.
  - Q. Okay. And you talked about the practice of hosing and potentially of burns. And then you said that there are some studies that may use, "surrogates" was your word, they use surrogates and say there is a possibility of an increased risk of infection. Is that right?
    - MS. LEWIS: Objection, form.
    - O. So which studies are those?
  - A. Albrecht, I believe, and -- If I had the studies in front of me I could tell you. I -- I --
  - Q. You have your citations in front of you, and I don't know if --
    - A. I think Albrecht, Reed.
- 22 O. So Albrecht, Reed.
- 23 A. Belani.
  - Q. Right, Belani.
- 25 A. Dasari maybe.

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- that then, based on the studies it -- it says there is this possibility, but some of the studies also in the conclusion or discussion section acknowledge that there are limitations to how those studies could or should be interpreted.
  - Q. Which are those studies?

And if you want to flip back to the end of your report, you can just tell me which ones you're talking about.

- A. I -- I think Belani is one. It's difficult for me to remember all of these from the top of my head.
- Q. Right. But you have your references at the end of the report right in front of you, and also the 14 Materials Considered on Exhibit 4; right?
  - A. Yeah, but I don't have -- I don't believe I brought Belani or...
    - Q. Yeah. So there's -- But there's -- So --

The end of your first opinion in this report you talk about essentially balancing risk between certain warming modalities and forced-air warming; is that right? "Other warming modalities may have risks not present in forced-air warming"?

- A. Which -- Which page, please?
- Q. Page 4. Immediately prior to number 2. The

- Q. Dasari, Legg, Leaper. Those all sound 1 familiar?
  - A. Yes.
  - Q. And these are the ones we talked about before that are not in your list of materials considered or on the list of citations at the end of your report; right?
    - A. Yes.
  - Q. What --

What are the risks, as you understand them, present in non-forced-air warming technologies?

- A. In the case of the electric heating
- 13 blanket --
  - Q. Right, the conductive blankets like VitaHEAT and HotDog, for example.
- 16 A. Right. You could -- You could get a -- If 17 the electrical element is exposed, there is a risk of 18 -- of a short-circuit.
  - Q. And do you have evidence of that, or are you just guessing that that could be a problem?
- A. I don't have evidence. The evidence may be 21 22 out there, but it --
  - Q. But as you sit here today you're not pointing to, like, a case report or something about dangers associated with VitaHEAT or HotDog.

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- A. No. I cannot point to anything specific. 1
- 2 Q. All right.
- 3 A. Yeah.

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- Q. Do you know of any other risks that may be 4 present in these conductive-warming modalities?
  - A. There is a potential risk for...

I'm not sure whether the -- the electric blanket is reused or disposable.

- Q. All right.
- 10 A. So if it -- if it is reused, then that's --
- there's an infection risk there from -- from reusing 11 12
- 13 Q. But as you sit here right now you don't know if it's a single-use item or a reusable; is that 14 15 right?
- A. Yeah. I was considering mostly forced-air 16 17 warming, so.
- Q. Well but if we're talking about conductive 18 modalities, right, like the VitaHEAT and the HotDog, 19 20 I'm just trying to understand, when you say that these other warming modalities may have risks not present in 21 22 forced-air warming, what are those risks.
- 23 So in conductive warming you said that 24 there's a possibility for short-circuit, but to your
- knowledge as you sit here there's no evidence you can

You know, speaking of which, the Bair Hugger is used at your hospital; right?

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- 3 A. Yes.
  - Q. Okay. What is your understanding of your hospital's relationship with 3M?
  - A. I -- I don't have direct knowledge of it, but I would say it's a hands-off relationship. They are a vendor, we are a customer.
  - Q. Do you have any idea what the size of your annual purchases are from 3M?
  - A. I don't, but I would suspect it's quite -quite large, because we -- although we are a college town, we are a tertiary medical care center. I believe we have now 50 to 60, or maybe even more, operating rooms.
    - Q. All right. And so you --

And the Bair Hugger is presumably not the 18 only product manufactured and distributed and sold by 3M that your hospital uses; fair?

- 20 A. I would assume so, yes.
  - Q. You probably have Post-it Notes at least;
- right? Everybody's got those. 22
- A. Yes. 23
- 24 Q. Probably quite a few other items
- 25 manufactured by 3M at your hospital.

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point to specifically about that; correct?

- A. That's correct.
- 3 Q. All right. And then the next thing you said 4 is if they're multiple-use modalities --
  - A. Umm-hmm?
- 6 Q. -- that there's a possibility that there could be infection or contamination risk; right? 7
  - A. Right.
- Q. But you don't know, as you sit here, if these are single-use products or multiple-use 10 products; correct?
  - A. Yes, but with the understanding also that even if it's a single use, sometimes it is reused. Off label, but it is reused.
  - Q. Okay. But we're going to go and we're going to try to assume accepted standards of medical practice, and that would be a departure from accepted standards of medical practice. Do you think that that's fair, if you know?
- 20 A. I don't -- I don't know if that's a legal term, "accepted." What I know is I've seen single-use 21 product reused. 22
- 23 Q. At your hospital?
- 24 A. I don't want to go there.
- 25 Q. I suspect not.

1 A. That's correct.

2 Q. And you'd expect that the relationship 3 between 3M and your hospital, given the prominence of 4 the University of Florida, is likely significant. Is 5 that fair?

MS. LEWIS: Objection, form.

- A. I don't know what you mean by "significant."
- Q. Okay. You expect that your hospital orders a great many of things from 3M. Fair?

MS. LEWIS: Objection, form.

- A. I -- I'm not in the purchasing department. 11
- What I see is the -- So I don't know what they order. 12
- 13 What I see is the end result. I see a lot of Bair
- Huggers, I see a lot of Bair Hugger blankets, so I 14
- assume somebody ordered it. 15
- 16 Q. Does your hospital use Bair Paws as well?
  - A. Yes, I believe so.
- 18 Q. All right. Turning to the second opinion you have here, you're talking about your opinion that 19
- 20 "Arizant and 3M acted reasonably in designing,
- developing, and marketing the Bair Hugger," and that's 21 a summary of your opinion; is that right? 22
- 23 A. Yes.
- 24 Q. And you base that on your review of the
- 25 510(k); is that right?

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A. Yes. 1

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- Q. Okay. And I don't see the actual 510(k) itself listed on either the materials -- the references at the end of your report or on the Materials Considered. Is that another omission?
- A. Yes. I'm sorry.
- Q. Okay. Do you have any idea why that's 7 8 missing?
- 9 A. Most likely because I reviewed it a long 10 time ago.
  - Q. And then you -- you say you reviewed the design and development history file, as well as other documents related to the design and testing of the Bair Hugger.

What other testing documents have you looked 15 at? 16

- 17 A. I've looked at the filtration tests.
- Q. And are those the documents that you 18 reference that are attached to -- or exhibits to Mr. 19 20 Crowder's deposition?
- 21 A. Some of them, yes.
- Q. All right. And now at the end of your 22 actual report there's no inter -- there's no reference 23 24 to internal tests of the Bair Hugger; is there?
  - A. Which tests? Which internal tests?

1 MS. LEWIS: Look at the one with your notes 2 on it, because that would tell you.

THE WITNESS: Yes, that's right. (Witness reviewing Exhibit 5.)

- A. Yeah, I believe there was one that Winston Tan did.
- Q. Did you see Mr. Tan's deposition, by the way?
  - A. No. I don't think so.
- 10 Q. All right. Do you have any idea why that wasn't provided to you? 11
- A. No. Well I don't know whether it was -- I 12 don't know. It's -- You're asking me a lot of things 13 14 out of memory. I don't know.
  - Q. All right. And I understand that that can be frustrating, but this is my one chance --
- A. Right. 18
  - Q. -- to ask for seven hours what the basis of your opinions is, and where it comes from.
- 20 A. Right.
  - Q. And when we don't have a complete list of materials considered, and when there are errors in the citations that limits our ability to ask questions to fully understand your opinions and the basis for those. So what --

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- Q. I don't know. I'm trying to figure that 1 2 out.
- 3 A. Okay.
  - Q. So, you know, on page 4 you say you have reviewed the design and development history file, as well as other documents related to the design and testing of the Bair Hugger. But there are no -- We've already established that footnote number 11 is incorrect, there's no other internal document that's listed as a reference in your report. Is that fair?
    - A. I -- Without looking at it, I can't --
  - Q. Well you can look at it.

If there's something that you can point me to, I'd be glad to look at it.

- A. (Witness reviewing exhibit.)
- 16 Q. Your references appear at pages fif -- 16 17 and 17.
  - A. And the question was?
  - Q. What testing did you review?

20 I see no internal documents or testing referenced on pages 15 and 16. 21

- A. Right. Yea, I don't -- Actually I think Mr.
- Assaad gave the 7132, so that's not -- that's not it. 23
- 24 Q. Right. Yep.
- A. (Witness reviewing exhibits.) 25

Were you provided any internal documents or any other testing that shows that Bair Hugger is safe and effective for use in orthopedic surgery?

A. When you say...

Is this within the context of internal testing, or are we on a different question?

Q. Both. Internal testing, external testing. If you -- If you can point me to a single study that shows that the Bair Hugger is safe for use in an orthopedic implant surgery.

MS. LEWIS: Well that's a different question.

> MS. ZIMMERMAN: Yes, I added "implant." MS. LEWIS: You also added "study." I

think the previous question was just any document. I could be wrong, but I think that's what I understood.

MS. ZIMMERMAN: No. I said "testing" last time, this time I said "study."

- Q. Either. You can provide study, testing 19 20 about orthopedic safety in implant surgery; internal document, external document. 21
- A. So the studies are, and -- and papers, none 22 23 of them, as we discussed, have established directly 24 that the Bair Hugger directly caused an infection in a
- patient during hip or those joint replacement 25

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Q. Okay. And I understand, doctor, that that's your interpretation of some of the studies that you did not cite to, but my question is different.

My question is: Are you aware of any study, done by 3M or anyone else, that confirms the use of Bair Hugger is safe for use in orthopedic implant surgery?

MS. LEWIS: That's what he just answered.

MS. ZIMMERMAN: No, it's not.

MS. LEWIS: He just said --

MS. ZIMMERMAN: No. His answer --

- Q. You can answer my question.
  - A. Okay. Please repeat the question.
  - Q. Sure.

"Are you aware of any study, done by 3M or anyone else, that confirms the use of Bair Hugger is safe for use in orthopedic implant surgery?"

- A. When you say "anyone else," like Moretti is included? If Moretti is included, then yes, I believe he showed that it is safe, the Bair Hugger is safe in -- in patients that had joint replacement.
  - Q. And by "safe," what do you mean?
  - A. The patients didn't get an infection.
- Q. All right. Anything besides Moretti?

You've worked on design for a simulation, it sounds like; is that right?

- A. No, an actual -- we built an actual 4 operating room --
  - Q. All right.

A. -- and actually manage a -- I'm struggling with the word -- it's not a discarded, but an operating room that was out -- not used, so I -- I now manage that operating room. It's a real operating room, it's not a simulated operating room.

- 11 Q. Umm-hmm. Is it "outdated" maybe the word, 12 or?
- 13 A. It was underused would be actually the 14 proper way to describe it.
- Q. All right. And are patients -- are operations actually conducted in this?
  - A. They used to be.
- Q. But they're not now?
  - A. Not now.
- Q. All right. And with respect to the hospital operating rooms at the University of Florida, you're
- 22 not the designer of the HVAC system, for example.
- 23 A. No.
- Q. All right. Somebody else did that at the

25 University of Florida.

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1 A. Huang also did a study, but it was not on 2 joint, I believe.

Q. Right.

A. But he, in his case too, the patients didn't get an -- an infection.

Q. Now with respect to this section of your report you cite to MERV ratings for filters, and ASHRAE standards. You don't personally have any experience designing an operating room; correct?

A. No, apart from the one that I helped design in the simulation center.

Q. All right. And so this is --

So designing an operating room and establishing filtration requirements, that's not something that is part of your -- your job at University of Florida; is it?

- A. Correct.
- Q. And are you a member of ASHRAE?
- 19 A. No. I am a member of the American Society

20 of Anesthesiologists Equipment and Facilities

- 21 Committee, and sometimes at our meetings, which is
- every year at least, and then sometimes through emails, we do discuss air handling.
- Q. All right. But -- But my question is really about operating room design. That's not something --

A. I believe it was probably the architect or the people -- they probably did it in consult --

3 consultation with the physical plant personnel of the hospital, as well as the infection people.

4 hospital, as well as the infection people.
5 O. I have no doubt that there were a

Q. I have no doubt that there were a lot of voices that would be heard in a meeting like that. But at any rate, you're not one of the

8 people that would be consulted with respect to
9 designing the operating room air supply system at the
10 University of Florida; correct?

A. Yes.

Q. All right. And you understand, you cite to ASHRAE standard 52.2 from 2012 to offer the opinion that the filter media in the Bair Hugger is -- is reasonable; is that right?

A. Yes.

- Q. Is there anything else that you are relying upon for that opinion?
  - A. The -- The tests.
- Q. Is there anything else that you're relying on for the opinion that this MERV 14 or the ASHRAE
- 22 52.2 provide sufficient filtration for medical
- 23 devices?
- A. Yes. Let me see if I --
- 25 Q. And which citation are you --

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Page 246 Page 248 A. I'm trying to pull it up. (Witness 1 that you have either relied upon or materials 1 reviewing documents.) 2 considered that are neither in your report, nor on 2 3 It's this one. It's the MERV parameters, 3 Exhibit -- Exhibit 4; correct? and it basically says it will catch all bacteria. 4 MS. LEWIS: Objection, form. 4 5 O. And where is this from? 5 A. There are --6 A. This is -- I -- It's a table. 6 There are some that I -- I read that I 7 7 MS. LEWIS: It says at the bottom, page didn't include. 8 "7." That came --8 Q. Do you think that that is a -- is good 9 Does it say page 7 at the bottom? 9 academic practice? MS. ZIMMERMAN: It does say page 7 at the 10 MS. LEWIS: Objection, form. 10 A. I -- I was not writing a paper, in my mind, 11 bottom. 11 12 so I didn't apply the same approach that I would use 12 MS. LEWIS: It came from Kuehn's report. MS. ZIMMERMAN: Michael Keen or Thomas for an academic paper. If I had known you were going 13 13 Kuehn? to ask me all these questions, I would have made sure 14 14 MS. LEWIS: Thomas. 15 I was exhaustive in what I listed. 15 BY MS. ZIMMERMAN: Q. Well, and you were provided, by way of 16 16 17 O. So this is --17 example, and we won't get into the details of it, but MS. LEWIS: So it was an exhibit to 18 you were provided the report of Dr. Said Elghobashi; 18 correct? Kuehn -- or page 7 of his report. 19 19 20 MS. ZIMMERMAN: All right. 20 A. Yes. 21 BY MS. ZIMMERMAN: 21 Q. Did it seem, upon your reading of that 22 report, that there were a significant number of 22 O. And that's not also listed in the citations 23 at the end or the Materials Considered; fair? 23 references and citations throughout the -- that paper? 24 A. (Witness reviewing exhibits.) No. 24 A. I don't recall. 25 25 Q. Did you review the report of Dr. William O. Correct? Page 247 Page 249 A. Yes. 1 Jarvis as well? 1 2 O. Yeah. 2 A. Yes. 3 3 MS. ZIMMERMAN: I think I better mark this Q. An infectious disease doctor disclosed by 4 just so we have it. 4 the plaintiffs. 5 (Discussion off the stenographic record.) 5 Would you agree that he also had many, many citations and references throughout the report he 6 (Lampotang Exhibit 8 marked for 6 identification.) provided in this case? 7 7 8 BY MS. ZIMMERMAN: 8 A. I don't recall. 9 Q. All right. So doctor, you have an extensive 9 Q. And you were provided with a copy of the CV, I think that we marked that as Exhibit 6. You've expert report of Dr. Yadin David. Do you remember Dr. 10 10 David's report? written many, many papers; right? 11 11 A. Yes. 12 12 A. Yes. 13 Q. And you -- you would agree that as you're 13 Q. Do you recall that it's 75-odd pages long? writing papers it's important that you provide 14 A. If you tell me that, I'm not going to -- I 14 references: correct? -- I -- I didn't pay attention to how many pages it 15 15 16 A. Yes. 16 Q. At any rate, we have -- we've certainly 17 17 Q. And you would agree with me, I hope, that as 18 we've gone through this deposition today that there 18 identified a number of errors in the citations at the are many, many omissions in terms of things that have end of your report; correct? 19 19 been either relied upon by you or considered by you 20 MS. LEWIS: Objection, form. 20 that are not in the report. Fair? A. Errors? I think that there was one, which 21 21 22 MS. LEWIS: Objection, form. 22 is the "xi" versus "xii," if I understood your 23 A. Please repeat the question. 23 question correctly. Q. As we've gone through this deposition today 24 Q. And a number of omissions in terms of 24 we have discovered many omissions in terms of things 25 articles that you rely upon. For example, Kurz is not

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cited in -- on pages 16 or 17; correct? 1

A. Yes.

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- 3 Q. But you explained that Kurz is somebody -that that paper is something that you rely upon in 4 5 support of your opinions; correct?
  - A. Yes. And it's -- it's -- it's -- it's very well known, and -- but yes, I -- I incorrectly assumed that because it's well known I didn't really...
    - Q. That you didn't need to be thorough?
- 10 A. No, it's not that I didn't need to be thorough. It's -- I don't -- You know, I did this. 11 I'm not a -- a professional expert witness. This is 12 13 not my main job. I have a job with the University. I
- don't write a lot of reports, so I think it was an 14 15 honest mistake.
- Q. All right. And I understand that, but, you 16 17 know, I -- I'm here on behalf of 3,000 people who take 17 this matter very, very seriously. You understand 18 19 that?
- 20 A. I do.
  - Q. And the -- the judges that have been tasked with overseeing this process take this case very, very seriously, and you would expect that; right?
    - A. Yes.
    - Q. All right. And one of the things that the

1 A. I'm -- I'm still not fully...

- Q. So when you're --
- A. There was a --

It is not that I didn't review the material, I did -- I didn't include it, and it was an honest mistake.

Q. And I accept that. And I hope that you understand that I'm doing the job that I'm tasked to do by the Court, which is to try to understand the assumptions you make, the conclusions you reach, and the basis for your conclusions so that we can make an argument and let the Court decide what is reliable and what should be allowed.

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Page 253

MS. LEWIS: And Dr. Lampotang is here answering your questions.

MS. ZIMMERMAN: We have been in a 16 deposition for many hours. 18

# BY MS. ZIMMERMAN:

- Q. Dr. Lampotang, what is -- would you agree 19 20 that ASHRAE standard 52.2 does not apply to medical 21 devices? Do you know if it applies to medical 22 devices?
- 23 A. I believe it applies to the air handling.
- 24 Q. All right. And that's different than 25

medical devices in the operating room; correct?

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judges are tasked with, and the parties, the lawyers that are involved with this case have a responsibility to do is to ensure that reliable opinions that assist the trier of fact are ultimately offered.

Would you -- Would you accept a paper missing references from -- from one of your students?

MS. LEWIS: Objection, argumentative.

- A. I don't know what the "trier effect" is, you had mentioned that. What is the "trier effect"?
- Q. Well the trier of fact in this case is going to be the jury, but first we have to convince the judge that the witnesses, such as yourself, offer reliable testimony and should be allowed to provide that testimony for a jury to consider.

So in trying to determine whether the opinions you've offered in this report are reliable we need to know what your methodology was, and we need to 17 be able to test the assumptions underlying the conclusions that you reach.

Does that seem like a reasonable process?

- A. Yeah, and I've shared with you what I -what I've done.
- Q. In many ways it seems very similar to the same kind of process that you outlined with respect to peer review; right?

- 1 A. Do you mean the specifications for medical 2 equipment?
  - Q. What I mean is does ASHRAE standard 52.2 apply to medical devices in an operating room?
  - A. There is a -- a -- It talks about filtration, and -- and some equipment filtration is -is relevant. But to answer your question, ASHRAE is about the air handling.
    - Q. So ASHRAE --

You agree with me that ASHRAE standard 52.2 is about air handling; correct?

- A. Yes. But in looking at -- at the -- for example, it talks about what kind of bacteria the air handling would trap, and they use the MERV parameter as a metric to say this is what it will trap. And --And in ASHRAE this table, rather, says that if you use 14 you will trap all bacteria.
- Q. So I understand what MERV does, and what the different ratings are.

20 But my question is whether ASHRAE standard 52.2, not the table in front of you, governs medical 21 22 devices.

- A. No.
  - Q. Okay. Thank you.
- In the next paragraph you say that there is

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Page 254

- an adhesive strip at the edge of the Bair Hugger
- warming blanket that's used to tape the blanket to the
- patient and prevent air from being directed to the surgical site. 4
- 5 A. Which page, please?
  - MS. LEWIS: Page 4.
  - Q. The very bottom of page 4.
- 8 A. Yes.

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- 9 Q. And is it your belief that the adhesive
- strip is sufficient to protect against the risk of 10 11 infection?
- 12 MS. LEWIS: Objection, form.
- 13 Q. You can answer.
- A. The -- The adhesive strip serves to isolate 14 the side where the blanket is from the surgical site, 15
- and there's also other drapes that are present. 16 17
  - Q. And you say, the warnings and labeling reasonably do not include a warning regarding the risk of infection, because there is no valid evidence of such an alleged risk (as discussed below).
- 21 That's from 4 to 5. Do you see that?
- 22 A. Yes.
- 23 Q. Why is it that you've determined that
- 24 Belani, Albrecht, Reed, Dasari, Legg and Leaper do not
- present evidence about a potential alleged risk of

- 1 Q. Oh, you have your Moretti study with you.
  - A. I don't know. Let me see. (Witness
- 3 reviewing documents.) 4
  - Q. Did you bring both the Moretti and the Huang studies?
- 6 A. Yeah, so...
- 7 I have the Moretti. Thank you. (Witness 8 reviewing document.) Yeah. So they describe their 9 limitations, --
  - Q. All right.
- 11 A. -- the sample size, et cetera. 12
  - Q. And that's a significant limitation;
- 13 correct?
  - A. The sample size -- Let me --
- Let me read the rest of it. (Witness 15
- reviewing document.) Yeah. So -- Yeah. The sample 16 17 size is a limitation.
  - Q. All right. And likewise there is -- there are limitations with Huang, too; right?
- 20 A. I would assume so.
  - Q. All right. Assume for a moment that the
- infection rate for PJIs is about 3 percent, so 3 22
- percent of patients that have a total hip or total 23
- 24 knee will ultimately have a periprosthetic joint
- infection. How large of a sample size would you need 25

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- infection? 1
- A. Well, one is they -- they didn't bring a 2
- case where there was actually an infection to the extent that one of the studies looked at patients, and
- 5 secondly, in the papers the authors, in the
- 6 limitations, acknowledge that there were limitations 7 to the study.
- 8 Q. And you'd agree that there are limitations 9 to most any study that's done; right?
- 10 A. Yes.
- Q. And you'd agree that it's good research 11 12 practice to voluntarily disclose known limitations; 13 correct?
- 14 A. Please repeat the question.
- 15 Q. Sure.

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You'd agree it's good research practice to voluntarily disclose known limitations.

- A. Publication practice, yes.
- Q. All right. In fact there are limitations in 19 20 Moretti; right?
- A. I would assume so. I -- I don't have 21
- 22 Moretti in front of me.
- 23 Q. All right. And you don't know what the 24 limitations are as you sit here today.
- MR. ASSAAD: Actually he does. 25

- 1 to do a study on this group?
- 2 MS. LEWIS: Objection, form.
  - Q. Do you know?
- 4 A. That's a --
  - That's a power analysis question. I'm not a -- an expert statistician.
- 7 Q. Okay. Do you think it'd be more than a 8 thousand patients?
  - MS. LEWIS: Objection, form.
  - Q. If you know.
- A. I don't know. I -- When I do my studies I 11
- 12 have a statistician who I rely upon, she is very
- 13 qualified, and that's what I do.
- Q. And that's something that researchers do 14
- frequently, right, somebody like you would work with a 15 16 statistician to handle the numbers part?
  - A. The -- The sample size issue is -- is not as
- 18 linear as we would wish or hope because sometimes
- there are limitations to how many people are available 19
- 20 to enroll, there are limitations about how many
- consent to be in the study once they are enrolled, 21
- then there are also methodological errors that end up 22 with some being discarded. So sometimes then we end 23
- up with what's called a sample of convenience, and 24
- that is sometimes accepted in the literature. 25

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- Q. Sometimes it's accepted in the literature, 1 2 and sometimes it's considered significantly 3 underpowered; is that fair?
  - A. In some cases, yes.

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O. Okay. And would you agree that both Moretti and Huang are significantly underpowered?

MS. LEWIS: Objection, form.

- A. I'm not a statistician so, you know, it's -it goes back again to the sample of convenience. So I don't know whether that's what they did, but -because I didn't talk to them, but there -- there -there is a -- a practical element, and I run into that all the time when I do my studies, where I very often cannot get what I would ideally like as a sample size. So that's the reality of doing research and publishing.
  - O. I understand that.

But given -- given that Huang and Moretti are both -- they're two of the 16 citations to your report, would you agree it's important to know if they are significantly underpowered before you rely upon them?

23 A. When a paper is accepted usually there is a 24 statis -- a statistical review. I'm not a statistical reviewer. I don't do that. So the implicit 25

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2 A. I --

MS. LEWIS: Objection, argumentative.

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- A. I -- I reviewed those studies, and I am going to repeat myself. I made an honest mistake in what I listed. If I had known this was a issue I would have listed everything.
- Q. So turning to page 5, you say that it's your opinion that Arizant and 3M took the high road and acted with poise and restraint in its official response to allegations about forced-air warming technology, sticking to the science and the facts, and undertaking additional testing of the Bair Hugger.

You go on to say: "I am not aware of any misrepresentations of the safety of the Bair Hugger or forced-air warming by Arizant/3M or any of its employees."

Is that -- Does that remain your opinion today?

20 A. Yes. There -- There --

> There was some confusion, I believe, about the filter.

- Q. Do you believe it was confusion?
  - A. Well I don't know. I don't work at 3M, so.
- 25 But from what I read, then when the -- when that --

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assumption is that when a paper is published that the reviewers were able to talk about it, were able to -to give feedback to the authors.

- Q. But as you were approaching the problem here, and the citations that you offered in support of your opinions and even the materials that you considered, you did not list Belani and Albrecht and Reed and Dasari and Legg and Leaper, and it seems -it seems a big piece of that is because of what you concluded to be limitations in those studies; is that fair?
- A. Part of it was just an omission, as we already went over.
- Q. Okay. And partly because you think that those -- those studies had limitations; right?
- A. Well I think we -- we just went over that most studies have limitations, so.
- Q. But you disregard, it seems, the conclusions reached by Belani and by Legg and, you know, these other study authors, but you didn't disregard the conclusions reached by Moretti and Huang, despite the limitations to those studies.

MS. LEWIS: Objection, form.

- O. Is that a --
  - Is that the approach of an objective

that was realized, it was -- the FDA was informed.

Q. Would it surprise you to know that 3M's internal people, in response to customer questions, say, quote, we do not want to disclose the actual filtration level, but it's sub-HEPA, end quote?

Does that sound like it's taking the high road, to you, doctor?

A. I don't have enough context to reply to that question. I'm sorry.

(Discussion off the stenographic record.) MS. ZIMMERMAN: We can take a break if you like.

THE REPORTER: Off the record, please. (Recess taken from 3:24 to 3:32 p.m.)

BY MS. ZIMMERMAN:

- Q. All right, doctor, I appreciate your patience with the ventilation system and a long day, and we'll try to get through this.
  - A. Thank you.
- 19 20 Q. Before we took the break we were -- we were 21 -- I was asking you some questions about your opinion about Arizant and 3M taking the high road. Have you 22 23 seen -- Have you been shown any documents about the 24 desire by Arizant and 3M to prevent ECRI from doing 25 their own study?

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- 1 A. I don't recall. I don't -- I don't know.
  - Q. So you haven't seen any documents that says our first step with ECRI should be preventing them from doing their own testing? You haven't seen any of those documents?
    - A. No, I didn't see that.
  - Q. You say that you're not aware of any misrepresentations of the safety of the Bair Hugger or the forced-air warming unit by Arizant or 3M or any of its employees.

Have you been shown any of the documents about the desire to represent that the filter was, quote, high efficiency .2 micron, end quote?

- A. I think that's what I was referring to when I said there was a mistake, and then the mistake was shared or --
- 17 Q. With the FDA?
- 18 A. Yeah, with the FDA.
- 19 Q. Right.

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20 And that mistake arose out of a -- an

21 inspection done in somewhere around 2009/2010; does 21

- that sound about right?A. I don't remember.
- A. I don't remember.Q. Okay. And does it sound familiar that
- 25 perhaps they corrected that mistake by Federal Express
  - perhaps they corrected that inistance by rederal Exp.

orthopedic surgeons at your hospital about increased particles during surgery? Do you know if that's something orthopedic surgeons at your hospital care about?

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Page 265

MS. LEWIS: Objection, form.

- A. I haven't talked to all of them, but one of them did share with me that he was looking at a ultraviolet portable cleaning element, and he did studies, and what he showed -- and he never -- he never published this, he didn't -- you know, he just shared it with me because I was part of evaluating whether we needed to use that ultraviolet. And I think his main finding was that the particle count or -- really went up when doors were opened.
  - Q. When the doors were opened?
- A. Yes.
- Q. All right. But in any event, the reason he was studying that was that an increased particle count was something they would be concerned about. Fair?
- A. Yes. And he -- he had -- he uses the Bair Hugger.
- Q. Okay. And in fact have you seen any documents from Michelle Hulse Stevens, the medical director in 3M's invention -- Infection Prevention Division, noting there is amazing concern about any

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letter in December of 2016, six years later?

MS. LEWIS: Objection, form.

- A. I don't remember. I -- I don't know. I don't have material to respond.
- Q. All right. And have you been shown any of the documents evidencing desires by various consultants and key opinion leaders for 3M requesting that additional studies, especially bacterial sampling studies, be done with respect to the Bair Hugger?
  - A. I'm sorry. It's been a long day.
- O. It has.
  - A. Can you repeat the question, please?
- Q. Have you been shown any of the documents evidencing desires by various consultants and key opinion leaders for 3M requesting that additional studies, especially bacterial sampling studies, be done with respect to the Bair Hugger?
  - A. I don't recall.
- Q. Do you know, for example, that Dr. Sessler had been urging additional study be done for many years?
- 22 A. Umm --
- O. You haven't seen those documents?
- A. I don't think so.
- Q. Okay. Are you aware of concerns by

particulates in the air during joint replacement
surgery, and almost uniform comment that forced-air
warming increases particulates in the air? Is that

4 something that's been shared with you in connection5 with your work on this case?

MS. LEWIS: Objection, form.

- A. This document is from who again?
- Q. Michelle Hulse Stevens, who is the medical director of 3M's Infection Prevention Division.
  - A. I -- Yeah, I think I may have seen it, but I can't -- I can't remember.
- Q. Have you been told before that decisions have been made at the highest level not to pursue additional testing about the Bair Hugger, inside the company?
  - A. I'm not aware of that.
- Q. All right. And have you been shown the war games document outlining Arizant's, quote, overall nightmare which would include if someone does a real study on forced-air warming and contamination? Are those documents that counsel has shared with you?

MS. LEWIS: Objection, form.

- A. Please repeat the question, please.
  - O. Sure.

Have you been shown the document that's

67 (Pages 262 to 265)

Page 266 Page 268 titled "war games"? 1 MS. LEWIS: Objection, form. 1 A. It's possible. I -- It's been -- It's been 2 A. Please repeat the question. 2 3 a long time ago. 3 Q. I said, you'd agree with me that whether it was 3M that took the high road, or Augustine, that the 4 MS. ZIMMERMAN: And I will mark this as an 5 viewpoint about who is correct or taking the high road exhibit so you can see it. 6 (Lampotang Exhibit 9 marked for 6 may depend on which articles you believe are credible. 7 identification.) 7 Is that fair? 8 8 BY MS. ZIMMERMAN: A. There is an element of that, but there's 9 Q. Is that a document that you've seen before? 9 also an element of, in my 30 years or more, 35 years I A. (Witness reviewing exhibit.) 10 guess, I can't remember, that I've been in this field 10 MS. LEWIS: Do I have one? I've never received an email like that that basically 11 11 12 MS. ZIMMERMAN: I wasn't going to use it. 12 paints a product in negative light, and it -- it's 13 O. And I'll represent to you, doctor, that the 13 just something I've never seen, so I -- and part of orange highlighting is my highlighting, it's not saying 3M took the high road is they -- they didn't go 14 14 highlighting from --15 15 to that level. A. Umm-hmm. 16 Q. Have you seen or been provided any of the 16 17 Q. -- Arizant or 3M? 17 marketing materials that 3M has circulated that 18 Is this a document you've seen before? 18 summarize 3M's criticisms of the -- of the various studies, including Albrecht and Reed and Harper and 19 A. (Witness reviewing exhibit.) I don't 19 20 believe so. 20 Dasani and Legg and Leaper and Belani? Q. But the document evidences a concern that 21 A. What is that docu --21 somebody might do a real study on forced-air warming 22 Is that a document? 22 and contamination; is that right? 23 O. Yes. 23 24 A. That's what it says, yes. 24 A. I don't believe so. 25 Q. All right. Do you think documents like this 25 Q. All right. And you haven't seen any of the Page 267 Page 269 are consistent with taking the high road? internal documents criticizing some of these well 1 2 MS. LEWIS: Object to form. respected academics made by 3M; have you? 2 3 3 A. Part -- Part of what I meant is I -- I MS. LEWIS: Objection, form. 4 receive, as a member of the American Society of 4 A. I don't recollect. Anesthesiologists, the emails Dr. Augustine has been 5 Q. All right. At any --6 sending out, and his latest one included parts of 6 At any rate, with respect to the opinions David's report, or what David had said, maybe not the that you have outlined in section 2 about --7 7 report, and -- and the company, in that sense, didn't 8 particularly with respect to warning, you have not

stoop to the level of the competitor that was making 10 those unsubstanti -- unsubstantiated claims.

Q. Well you would agree that whether or not the claims of Dr. Augustine are unsubstantiated depend significantly on whether or not you believe the conclusions reached by the studies that you elected not to include in your study -- or in your report, including Belani and Albrecht and Reed, Dasari, Legg, Leaper, Harper, McGovern.

17 18 A. I -- I think it mischaracterizes that I elected not to include them. I said a few times I 19 20 made an honest mistake.

Q. Okay. But you would agree with me, I think, that who took -- who took the high road and who may be coloring the viewpoint in the anesthesiology community

depends on which articles you believe are credible. 24

Is that fair? 25

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personally been qualified previously as a warnings expert; have you?

A. No.

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Q. All right. Have you ever --

13 Have you ever written a warning on a medical 14 device?

15 A. It is possible.

Q. That you did write a warning?

A. It is possible, yes.

18 Q. You -- You don't remember if you wrote a 19 warning, or?

A. I'm saying it's possible because I was part of a development team for the Sedasys conscious sedation machine, and we did go through labeling, warning and all that.

24 Q. All right. And during that process it was 25 important for your team to understand the risks

Page 270 Page 272 associated with that particular device; right? changed the filter on the Bair Hugger. 1 1 A. The "device" being the Sedasys? 2 2 Q. So it's your assumption that they changed 3 Q. Yes. 3 the filter and didn't clean out whatever dust may be A. Yes, we did a -- we did a FMEA, yes. 4 4 inside the machine? 5 O. Okay. And that's a Failure Mode Effects 5 MS. LEWIS: Objection, form. 6 Analysis? 6 Q. I'm trying to understand what your basis is. 7 A. It is Failure Mode Effects Analysis, yes. 7 A. The basis is the -- in writing the paper 8 Q. Okay. And you pre -- your team prepared 8 they detailed what they did as far as cleaning the instructions for use with respect to that device; is 9 dust. 10 Q. And they say they cleaned the dust out of 10 that right? all the machines; correct? 11 A. It was not my team. 11 MS. LEWIS: Objection, form. 12 Q. Okay. 12 A. I mean, in the sense of I didn't direct it. 13 13 A. I -- I actually have the paper here. I was a consultant. And, yes, the instructions for 14 14 Q. Okay. use was a part of that. MS. LEWIS: What are you looking for, 15 15 Q. And you would agree that appropriate 16 16 Bernards? 17 instructions for use include warnings about known 17 THE WITNESS: Yeah, Bernards. I thought I 18 risks; correct? 18 had it. A. Yes. 19 19 A. I -- I -- I can't recall exactly what they 20 Q. All right. And providing adequate warnings 20 said. is necessary to protect the safety of the patient. 21 21 Q. So --22 22 Fair? MS. LEWIS: Hold on. I'll get it. You can 23 23 keep going, but I'll get it for you. 24 Q. Turning to number 4, you -- you say that the 24 MS. ZIMMERMAN: And counsel, is this your real-world data from an actual infection outbreak, you 25 copy or his copy? Page 271 Page 273 say the Bair Hugger filter is effective at trapping 1 MS. LEWIS: What do you mean? Acinetobacter baumannii; is that right? 2 MS. ZIMMERMAN: That you're looking for? 2 3 A. Which paragraph in chapter 4? MS. LEWIS: I'm looking for Bernards. 3 MS. ZIMMERMAN: Right. But the copy that 4 Q. It just starts at 4, and I'm going to flip 4 5 over to 5. I just wanted to read --5 you're looking for in the Redrope is your copy of the 6 6 article, or the witness's copy? A. Oh. Q. -- the title first. 7 MS. LEWIS: This is my Redrope, if that's 7 8 Oh, it's at the bottom of page 5. I'm 8 what you're asking. 9 9 MS. ZIMMERMAN: Yeah, that's what I'm sorry. A. Oh, okay. 10 10 asking. Q. There you are. 11 11 We have not marked Bernards at this point. 12 A. Yes. Umm-hmm. 12 MS. LEWIS: (Handing.) Q. In this section your opinions are based on 13 13 THE WITNESS: Thank you. the Bernards paper; is that right? BY MS. ZIMMERMAN: 14 14 15 A. That is correct. 15 Q. And can you underline where you see Q. And you conclude, halfway down this page, 16 confirmation that the Bair Hugger was not cleaned? 16 "...we can assume that the Bair Hugger was not 17 A. What I wrote in the report is they 17 18 cleaned." Is that right? 18 specifically mentioned cleaning, even saying they blew the dust off the CVVH, they -- and they removed the A. Yes. 19 19 20 Q. What is your basis for that? 20 dust from the ventilator. And as regards the Bair A. My basis is the authors specifically said Hugger all they said was, we changed the air filter. 21 21 Q. All right. 22 that they cleaned dust off the ventilator, they 22 specifically said they cleaned dust from the CVVH 23 A. I'm sorry, the filter. 23 machine, and they didn't say that they cleaned dust 24 Q. And that is the full basis by which you say 25 from the Bair Hugger. What they did say is that they "we can assume that the Bair Hugger was not cleaned"?

Page 274 Page 276 1 A. Yes. 1 Q. -- it's not on Exhibit 4; right? 2 2 A. Yeah, you -- Yeah. Q. All right. Now in your -- in your expert report you are critical of Dr. Jarvis for his citation 3 Q. And you're not an epidemiologist; fair? to, or I guess reliance upon Bernards. That's the 4 5 only criticism that you include in your report with 5 O. And you're not going to be offering any 6 respect to Dr. Jarvis's report. Is that the sum total 6 testimony at trial on this matter to rebut Dr. Samet's of your rebuttal of his testimony? 7 report; is that fair? 7 8 I assume that it is the sum total of your 8 A. Yeah. criticism of Dr. Jarvis's report, given there is no 9 Q. All right. Next up you -- we -- you were provided the expert report of Dr. Michael Stonnington, other detailed rebuttal. Is that fair? 10 10 A. If you say so, yes. Umm-hmm. I think, although it does not appear on Exhibit 4. 11 11 12 Q. And just as I go down a list. So that's Dr. 12 Do you recall reading his report? 13 Jarvis. 13 A. Yes. 14 With respect to Dan Koenigshofer, you've 14 Q. He's an orthopedic surgeon? been provided a copy of his report? 15 15 A. Yes. A. Yes. Q. And you're not an orthopedic surgeon, we 16 16 17 Q. And you note, towards the bottom of page 13 17 covered that earlier; right? of your report, that's the only place Dan 18 18 A. Yes. Koenigshofer's name even appears in your report, it 19 Q. And so you would defer to orthopedic 19 says, Table 8, the MERV Efficiency Parameters on page 20 20 surgeons on matters of orthopedic surgery; is that 21 12 of the Koenigshofer report states combustion smoke 21 fair? is less than .3 microns and that most smoke is .3 to 1 22 22 A. Yes. 23 micron. And then, I would add, in size. 23 Q. Okay. And in any event, the report that 24 Would you agree that's not -- that's not a 24 you've prepared in this matter, Exhibit 3, does not 25 criticism that you're making of Dr. Koenigshofer's 25 mention Dr. Stonnington at all, and I trust that means Page 275 Page 277 1 you have no criticisms of his report either. Fair? report. Fair? 1 MS. LEWIS: Objection, form. 2 A. Well I didn't mention it in my report. 2 3 3 Q. All right. Thank you. A. Yeah. It's a -- It's a statement. MS. ZIMMERMAN: This Costco pen, the lid 4 Q. And just citing to the same table that he 4 5 cites to; is that right? 5 falls off of it everywhere I go. Can't take me anywhere. 6 A. Yes. 6 7 7 Q. Okay. And so you'd agree with me you don't BY MS. ZIMMERMAN: have any other disclosed rebuttal of Dr. 8 Q. And we talked about Dr. Elghobashi. You 9 Koenigshofer's report? 9 were provided his report and you're not -- you're not 10 10 If that's the only place here that -a computational fluid dynamics engineer and you're not A. Yeah. If that's the only place, yes. going to be providing a rebuttal to his report as 11 11 12 Q. Similarly, Mike -- Michael Buck, his expert 12 well. Fair? 13 report was provided to you; correct? 13 A. I would not rebut his CFD, but I can 14 A. Yes. 14 discuss, I believe, his simplifying assumptions --15 Q. And it appears on Exhibit 4, and you have 15 Q. And in any event -not offered any criticisms or rebuttals of the -- of 16 A. -- and also the setup, because I believe, 16 from reviewing his report, that an important element, Mr. Buck's report; is that correct? 17 17 18 A. I believe so. 18 a large element, physically large element of the Q. And we discussed earlier Dr. Jonathan Samet operating room was missing, and that's the anesthesia 19 19 from the Keck School. He's an epidemiologist, and I 20 machine. 20 don't believe his report was provided to you; is that Q. Okay. And doctor, will you -- will you 21 21 22 right? 22 point to me anywhere in your report where Dr. 23 MS. LEWIS: Objection, form. 23 Elghobashi's name appears or where the criticisms you 24 Q. Well at any rate --24 have of his report appear? 25 A. Yeah. 25 A. I don't believe I -- I included it in my

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- 1 report.
- 2 Q. All right. So you'd agree that there are no criticisms of Dr. Elghobashi's report in your report.
- 4 Fair?

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- 5 A. In my report, no.
  - Q. Okay. And then that leaves us with Dr.
- 7 David; correct? Yadin David. Do you recall reviewing 8 his report?
- 9 A. Yes.
- 10 Q. All right. And he is a doctor and an
- engineer, I believe, in Texas? 11
- 12 A. That is correct, yes.
- Q. Okay. And you mention his name in three 13 different places in your report. The first is on page 14 6, and it is the second word on the second line of the 15 first full paragraph. 16
- 17 A. All right.
- Q. And again is with respect to the Bernards 18 study, and you -- you say that Dr. David is incorrect 19
- and misleading in his description of the Bernards 20
- 21 study; is that right?
- 22 A. Yes.

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- 23 Q. Okay. And then you -- you quote, I assume
- 24 this is to Dr. David's report, it says, quote, after
- cleaning, underscore, and filter replacement, the 25

- authors did: correct?
  - A. That is correct.
- 3 Q. All right.
  - A. There is also another companion paper which
- 5 I believe I quoted. I think it's Van den Broek or
- 6 something. And it may be --

Yes, it's on page 2 of Exhibit 5.

- Q. Okay. The epidemiology of multiple
- Acinetobacter outbreaks in The Netherlands during the 9 10 period of 1999 through 2001?
  - A. Yes.
  - Q. All right. And it's your understanding that that is a companion to the Bernards study?
  - A. It's not a companion. I believe it
- 15 describes some of that same outbreak.
- 16 Q. And so it's your understanding that the authors in Van den Broek communicated or otherwise 17
- made the same assumption you did with respect to what 18
- was done in the Bernards study? 19
- A. Please repeat the question. 20
  - Q. I will try.
- 22 It's your understanding that the authors in
- 23 Van den Broek communicated or otherwi -- communicated
- 24 with the Bernards study people, or otherwise they made
- 25 the same assumption that you did with respect to what

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outbreak stopped, end parentheses. And it seems from your report the underscore is your emphasis added; is 2 3 that right?

- A. Yes. I added the emphasis.
- 5 Q. Have you spoken with the authors of the 6 Bernards study?
  - A. No, I have not.
  - Q. Okay. And so it is your interpretation, or it's your assumption, based on the reasons we talked about earlier, that the Bair Hugger filter was replaced but nothing else on the machine was cleaned; is that right?
  - A. That's what they -- they -- They were silent about cleaning the machine. They didn't say they -they cleaned -- I'm sorry. Let me take that again.

They didn't say they cleaned the Bair Hugger, they said they cleaned the ventilator and the CVVH. So I would not understand why they went to explicitly say they cleaned two pieces of equipment but would not say that they cleaned the third piece.

- Q. Okay.
- A. They only say that they changed the filter.
- 23 Q. All right. And you'd agreed with me that
- you have explained the basis of your assumption, but 24 that is your assumption of what the Bernards article

was done in Bernards. Is that fair?

A. No. That's not what I said.

I'm saying Van den Broek -- because I think one of the quotes I have, I was reading at my report yesterday, and -- and I saw a quote that I could not find in the Bernards paper. Oh, and actually yes.

So Van den Broek is the senior author on Bernards, and then Van den Broek is the first author on the other paper.

Q. Okay.

A. So -- So it is possible, I can't find the --11 12 there -- there is a quote. And when I looked here I 13 couldn't find that quote, and I knew it was a quote 14 because I put it in quote marks, and I couldn't find 15 it here, so.

O. So I don't --

I mean, first of all, this Van den Broek is not cited.

- A. It is in --
- 20 O. I know it's on Exhibit 4, but it's not in the -- in the 16 at the end of your report. I don't 21 22 -- I don't see the quote that you're talking about.

Is it possible that it was in a previous draft of your report and didn't make it to this one?

A. No. I -- I reviewed it yesterday, so I'm

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Page 282 Page 284

- pretty sure. It's -- It's in here, but I 1 can't -- I can't locate it right now. 2
- Q. So you think that there's a quote from Van den Broek, but you're not sure where. 4
  - A. It's in the report, yes.
- 6 Q. Well I can't see it, and I won't pretend to 7 have read it more -- it's possible that I've missed 8 it, but I -- there's no citation to it, and with a quick review that I just did I don't see it in here.
- 10 A. Okay.

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- 11 Q. At any rate, it seems that you and Dr. David have different assumptions about what happened in the 12 13 Bernards paper; is that correct? With respect to cleaning the Bair Hugger. 14
  - A. A different interpretation.
- Q. Yes. And that's your first criticism of Dr. 16 17 David; is that fair?
- A. If that's the first instance in this report, 18
- 19 ves. 20 Q. All right. Then the second is on page 11.
- Again it says "The David report." You see that right 21 in the middle of the page? "The David report mentions 22
- the Mistral convective forced air warming system that 23 24 uses HEPA filters"?
- 25 A. Yes.

- theater -- "nothing that blows air should be in an 1
- 2 operating theater, if possible"; right?
  - A. Yes, that's what I quote.
    - Q. And Dr. David and Dr. Jarvis are both
- 5 quoting to the CDC draft HICPAC meeting minutes from
- 6 November 5th and 6th of 2015; right? 7
  - MS. LEWIS: Objection, form.
- 8 Q. Do you know?
  - A. I assume that's what they were doing, yes.
- 10 Q. All right. And do you know if the -- if the
  - CDC has recommended essentially no nonessential items that blow air should be present in an operating room?

MS. LEWIS: Objection, form.

- A. These are -- These are the minutes of a
- 15 HICPAC meeting. I can't remember, sitting here,
- 16 whether it was converted into guidelines, and I'm
- 17 referring here to what David and Jarvis --
- 18 O. Have cited to.
  - A. -- quoted, yeah.
- 20 Q. And in your work at the University of
- 21 Florida you've become aware of the Sorin 3T
- 22 heater-cooler machine problem; correct?
- 23 A. Yes.
  - Q. And you understand that HICPAC found that
- 25 the environment inside a heater cooler was, quote,

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O. And you talk about whether or not the risk 1 is, quote unquote, theoretical. You see that? 2

- A. Yes.
- 3 4 Q. But as we talked about earlier, there are 5 certainly some theories that -- that you believe in; right? There's some theories, like the theory about 7 global warming, that there may be a risk there that's theoretical at this point; fair? 8
- 9 A. Yes.

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- Q. Do you think that it's good medical or engineering practice to dismiss a risk because it is merely theoretical?
- A. You also have to look at the evidence, so when -- when I say it's theoretical, there is also the fact that there is no proven instance where the Bair Hugger caused a patient to be infected.
- Q. So you're involved in anesthesia, and you're aware of the Sorin 3T heater-cooler recall; right?
- A. The heater-cooler unit?
- 20 O. Yes.
- 21 A. Yes.
- 22 Q. And this comes up to some extent in opinion
- 23 number 10 that starts on page 12; right? And you talk about the implications of -- of both Dr. David and Dr.
- Jarvis saying, nothing that blows air in the operating

- perfect for growing all manner of organisms, end 1
- 2 quote; right? 3
  - A. I don't have the --
- 4 Is this in the report?
  - Q. Are you aware that that is what HICPAC --
- 6 A. Paraphrasing?
- 7 Q. Yeah.
- 8 A. Yes.
- 9 Q. Okay. And you'd agree that bacteria need a 10 couple things to grow; right?
- Do you know? They need air? 11
  - A. Some don't.
- Q. Some don't. 13
- 14 A. Yeah.
  - Q. Do they need si -- sugar?
- 16 A. I would assume they need some kind of
- 17 nutrient, it may not necessarily be sugar.
- 18 Q. Something sweet maybe? My kids live on things like Kool-Aid and Tang. 19
- 20 A. Yeah. Not -- Not necessarily.
- Q. But at any rate, the HICPAC found that the 21
- 22 environment inside the heater cooler was hospitable to 23 the particular bacteria involved; right?
  - A. I believe so, yes.
  - Q. And that bacteria was a Mycobacterium

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- chimaera; is that right? 1
  - A. I go by what you say. I -- Unless I wrote it down. I know they found bacteria, I don't -- I can't tell you whether it was Mycobacterium.
  - Q. And you note -- you note in your report that one of the HICPAC findings was that the inside of the Sorin 3T heater-cooler machine was non-cleanable; right?
    - A. Yes. Non-cleanable foam.
- 10 Q. Okay.
- 11 A. Yes.

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12 Q. And then it goes on: The situation is 13 perfect for growing all manner of organisms.

Have you been shown internal 3M documents that show that the inside of the Bair Hugger machine and the hose are likewise very hospitable for growing bacteria?

MS. LEWIS: Objection, form. 18

- 19 A. "Hospitable."
- 20 Q. "Hospitable."
- A. I -- I don't recall seeing such a document, 21

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- 23 Q. Okav.
- 24 A. -- but it is possible. It's a long time

25 ago.

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- 1 Mycobacterium chimaera infections in their heart 2
- tissue thought that was pretty peculiar because of the 3 nature of the rare bacteria.

Is that consistent with your kind of recollection about the issues involving the heater-cooler device?

- A. Yeah, I believe so.
- Q. And do you think it's possible that that research team likely made the connection ultimately because of the nature of that very rare bacteria?

MS. LEWIS: Objection, form.

- A. Please repeat the question.
- O. Sure.

Do you think that it's possible that the research team likely made the connection between what turns out to be contaminated medical devices, the heater coolers, and the infections in these patients really because the bacterium itself was so rare?

MS. LEWIS: Same objection.

- 20 A. I -- I have not talked with the researchers 21 so I can't say how they honed in on the mechanism.
- 22 Q. All right. Do you know anything about the
- 23 Mycobacterium chimaera bacteria that makes it
- 24 particularly susceptible to aerosolization?

25 Let me --

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O. All right. And in fact Dr. David cites to 1 some of those documents in his report that you 2 3 reviewed; right?

MS. LEWIS: Objection, form.

- Q. Let's turn back a little bit more specifically to the Sorin 3T heater cooler. Do you understand that that recall came following years of diligent case reports by involved physicians, ultimately a series of research papers, and
- experiments? Do you understand that? 10 11

A. Yes.

- Q. Okay. And the Mycobacterium chimaera that was involved in there, in the heater-cooler recall, it's a -- it's a pretty rare bacteria. Do you know that?
- 16 A. I believe I recall seeing -- reading that, 17 18
  - Q. All right. And do you know that it's not something that you would typically see in the heart, for example, it's more of a lung-based infection like tuberculosis?
    - A. I wasn't area of that.
  - Q. Okay. And so perhaps you know from reading some of the minutes, that treating physicians for a couple of patients in Europe who came down with

- A. No, I don't. 1
- 2 Q. Yeah. There --
  - A. Yeah.
  - Q. As you sit here today there's nothing particular about the shape of that bacteria, to your knowledge, that would make it more likely to be transported through the air. Is that fair?

MS. LEWIS: Object to form.

- A. I didn't look into that part.
- Q. Okay. You know, as you sit here you don't 10 know if that bacteria is bigger or smaller, you know, 11 12 heavier than other bacteria; do you?
- 13 A. I don't, but I know the range of bacteria, 14

- 15 Q. Okay.
- 16 A. -- the range of sizes.
- Q. Have you seen the International Consensus on 18 Periprosthetic Joint Infection?
  - Â. Yes.
  - Q. Do you understand that the international community recognizes the theoretical risk that forced-air warming such as Bair Hugger may cause periprosthetic joint infections?

MS. LEWIS: Objection, form.

25 A. Please repeat the question. Page 289

Page 290 Page 292 Q. Right. 1 MS. LEWIS: (Document handed to the 1 2 witness.) 2 So you cite to the international consensus on prevention of periprosthetic joint infections, I 3 THE WITNESS: Thank you. 4 4 believe. MR. ASSAAD: Mark it. 5 5 MS. ZIMMERMAN: Pardon me? I don't see it. 6 Is the international consensus document 6 We'll mark that. 7 something that you considered but potentially omitted 7 And I'm going to just instruct you that 8 from your list? 8 that is inappropriate coaching a witness at a 9 A. I -- I looked at it and, yeah, it should 9 deposition. Just because it's -have been on the list. 10 MS. LEWIS: You're asking him a --10 MS. ZIMMERMAN: -- the last expert dep --11 Q. Okay. And so you recognize, because you did 11 review it, that the international community recognizes 12 12 No, no, no, no, no. the theoretical risk posed by forced-air warming; 13 13 MS. LEWIS: You're asking him about a correct? 14 14 document. A. It recognized the theoretical risk, but it 15 15 MS. ZIMMERMAN: Counsel, that is absolutely also added that there -- there is no indication to inappropriate, and you know it. 16 16 change practice -- I'm paraphrasing --17 And just because it's the last deposition 17 18 in general causation does not mean you get to coach 18 Q. Right. the witness by putting documents in front of him that A. -- there is no indication --19 19 Q. We both are. you think he should have. All right? 20 20 A. -- there is no indication to change practice 21 MS. LEWIS: You're asking --21 MS. ZIMMERMAN: That's not appropriate. 22 22 based on that, quote unquote, theoretical risk. 23 Q. And you'd agree that the international 23 MS. LEWIS: You asked the witness --24 consensus statement also says that further research is 24 MS. ZIMMERMAN: It's not appropriate. needed into the issue; correct? 25 MS. LEWIS: -- about a document, but you're 25 Page 291 Page 293 MS. LEWIS: Objection, form. 1 not showing him the document. 1 2 2 MS. ZIMMERMAN: I --A. It's in the --3 If it's in the report. So if you tell me MS. LEWIS: I put the document --3 4 it's there, then I will assume, in good faith, it's 4 MS. ZIMMERMAN: Under no circumstances is 5 there. 5 that appropriate behavior, counsel. You know better. MS. LEWIS: So I put the document that 6 Q. Okay. And given the international 6 community's -- the international consensus statement, 7 you're asking him about in front of him so he can 7 that means there's agreement that the theoretical risk 8 look at the document. 9 is a valid concern and needs to be looked at. You 9 MS. ZIMMERMAN: And I reiterate that that 10 10 is inappropriate practice and procedure, and if agree? 11 that's how people do things at 3M or Blackwell Burke, 11 A. Please -it's in violation of the rules. This isn't your 12 MS. LEWIS: Objection, form. 12 deposition. You're not allowed to behave that way. 13 A. Please repeat. 13 We're going to mark the deposi -- the 14 O. Yes. 14 15 Given that -- the international consensus 15 exhibit. statement, you'd agree that that means there is an 16 (Lampotang Exhibit 10 marked for 16 identification.) agreement that the theoretical risk is a valid concern 17 17 18 and needs to be looked at. 18 (Discussion off the stenographic MS. LEWIS: Objection, form. 19 19 record.) 20 Q. And by "theoretical risk" I mean risk that 20 MS. ZIMMERMAN: Yeah, we'll mark it and forced-air warming causes an increase in the risk of we're not going to have it in front of him. 21 21 22 PJIs. 22 BY MS. ZIMMERMAN: 23 MS. LEWIS: Objection, form. 23 Q. I'm sorry that you see lawyers raising their 24 A. They -- They spelled out -- they mentioned a 24 voices. That's not how things are done here. There theoretical risk, and -- but that --25 is a protocol.

Page 294 Page 296 MS. LEWIS: Really? 1 Q. Yes. 1 2 A. Umm-hmm. 2 MS. ZIMMERMAN: Yes. 3 MS. LEWIS: So you're marking it as an 3 Q. And so they recognized the theoretical risk and they recommended additional study on the matter; exhibit but you're not going to put it in front of 4 4 5 5 him? correct? 6 MS. ZIMMERMAN: That's correct. I'm going 6 A. I believe so, but I -- I can't tell you from 7 to mark the exhibit that you offered to the witness, 7 memory whether they did. 8 8 Q. Okay. And -- And when, if you know, did the 9 MS. LEWIS: Oh, okay. 9 international consensus document, when was it MS. ZIMMERMAN: -- took -- as written published? 10 10 11 coaching in connection with a question that was 11 A. I don't recall. 12 Q. Was it in 2017? 12 pending. 13 MS. LEWIS: Okay. 13 A. I don't recall. I'm sorry. MS. ZIMMERMAN: It's marked and it's not in 14 Q. All right. Do you know whether or not the 14 international consensus was sponsored by 3M? 15 front of the witness. 15 MS. LEWIS: Okay. A. I -- I don't know. 16 16 17 THE VIDEOGRAPHER: We have 11 minutes 17 Q. You'd agree that this document, the 18 international consensus document is several years old; 18 remaining. MS. ZIMMERMAN: Thank you. correct? 19 19 20 I'm going to take a quick break. 20 A. I -- I don't know when -- when it came out, 21 THE REPORTER: Off the record, please. 21 so. I already said I don't know when it came out. (Recess taken from 4:24 to 4:29 p.m.) 22 Q. All right. And do you know that -- that the 22 medical director of the infections prevention 23 BY MS. ZIMMERMAN: 23 24 Q. Doctor, I just have a few more questions 24 division, Michelle Hulse Stevens, who we mentioned earlier in your deposition, that she was present for 25 25 here. Page 295 Page 297 With respect to the international consensus 1 the meeting of the international consensus? Do you 1 that we were discussing prior to the break, you know that? 2 recognize that the international consensus has 3 A. No. I didn't know that. 3 4 recognized the theoretical risk of surgical-site 4 Q. And despite the fact that these 5 infection; right? 5 recommendations have been outstanding now for a number A. Yes, and also that -- that there is no need of years, do you think it's -- it's good responsible 6 6 practice for a company to refuse to do the studies 7 to change practice. 7 Q. Yes, but -that the international consensus recommends be done? 8 8 9 (Interruption by the reporter.) 9 A. I am not aware that I --A. There's no need --10 I was not aware that they refused to do the 10 THE WITNESS: I'm Sorry. I'm getting --11 studies. 11 12 12 Q. All right. And one last thing, and I do It's late. understand --13 A. They -- They said there was no need to 13 change practice, I'm paraphrasing, I -- I -- it's not 14 Well we've talked a lot about the materials 14 that are cited and the materials considered on your the exact words. 15 15 16 Q. You understand, from your review prior to 16 various reports, and we know that at least the this deposition today, that the international international consensus document was unintentionally 17 17 18 consensus recognized the theoretical risk that 18 omitted; right? A. Yes. forced-air warming blankets increased the risk of 19 19 surgical-site infection; correct? 20 Q. And we know that the Kurz study was 20 unintentionally omitted; correct? MS. LEWIS: Objection, form. 21 21 22 22 Q. That's --A. Yes. Q. We also know that the Sessler study was 23 And I understand there was --23 24 A. It's in the --24 unintentionally omitted; correct? 25 A. Yes. 25 It's in the report, yes.

Page 298 Page 300 Q. We know that Legg was unintentionally report and the Materials Considered document, you have 1 provided information -- or you have provided that you 2 omitted; right? 3 A. Yes. have reviewed those documents and some of those Q. And do you know if -- there's more than one documents may or may not influence or had an effect on 4 4 5 5 your opinion; correct? Legg study? 6 A. Yes. 6 MS. ZIMMERMAN: Object to form. 7 7 Q. All right. And both were unintentionally A. Yes. 8 8 Q. Go to your study -- I'm sorry -- your expert omitted? report, page 13. Under number 11, which is the fire 9 9 A. Yes. Q. Do you understand that Dr. Dasari's paper 10 in the Bair Hugger, the Moon --10 was unintentionally omitted from your list; correct? A. Yes. 11 11 12 Q. -- study; correct? 12 A. Yes. Q. And Dr. Reed's study was unintentionally 13 You see where, on -- in the first paragraph, 13 omitted from your list? 14 third line, you say, "multiple expert reports"? 14 15 A. Yes. 15 A. Yes. Q. And Dr. Leaper's study was unintentionally 16 Q. Do you see that? 16 omitted from the list; correct? And you don't list the name of the 17 17 18 particular experts, but are you saying there some of 18 A. Yes. Q. And so we have identified at least 10 the expert reports that are in this MDL? 19 19 MS. ZIMMERMAN: Object to form. 20 different articles, peer-reviewed studies that were 20 unintentionally omitted from your list of references; 21 A. Yes. 21 22 Q. So even though you did not list the 22 correct? particular experts, you do, under section 11 of your 23 A. Yes. 23 24 Q. And this is in connection with a paper where 24 report, do have some criticism of reference to some you cite a total of 16 studies; correct? 25 opinions in other expert reports concerning soot; Page 299 Page 301 A. I didn't count. 1 correct? 1 2 Q. All right. 2 MS. ZIMMERMAN: Object to form. 3 3 MS. ZIMMERMAN: I have nothing further at A. Yes. 4 this time. 4 Q. So your expert report reflects the criticism 5 MS. LEWIS: How many minutes do I have? 5 that you have with respect to the soot issue; correct? MS. ZIMMERMAN: Object to form. 6 THE VIDEOGRAPHER: Can we go off the record 6 7 7 A. Yes. a second? 8 MS. LEWIS: Sure. 8 Q. Can you pick up Exhibit Number 10, and 9 THE REPORTER: Off the record, please. 9 Exhibit Number 10 is the international consensus 10 (Discussion off the record.) 10 meeting document that you and Ms. Zimmerman were **EXAMINATION** 11 talking about; correct? 11 12 BY MS. LEWIS: 12 MS. ZIMMERMAN: Object to form. Q. It doesn't show on there. Does that look 13 Q. Dr. Lampotang, you just finished some 13 questioning with Ms. Zimmerman about the things that familiar? Look at the bottom of that first page. Do 14 14 you have testified today that were inadvertently 15 you see question 15? 15 16 omitted from your report; correct? 16 A. Oh yes. Right. Yes. Umm-hmm. 17 Q. Okay. So this is what you two were talking 17 A. Yes. about; correct? 18 Q. Even though those documents or studies or 18 whatever was discussed were omitted, you have been A. Yes. Yes. 19 19 sitting here today answering Ms. Zimmerman's questions 20 Q. And Ms. Zimmerman was asking you questions 20 about what you did, what you reviewed, and on what you about this document but did not put the document in 21 21 rely; correct? front of you so that you could look at the document 22 22 with respect to what the document said; correct? 23 A. Yes. 23 24 Q. So even though those documents or studies or 24 A. Yes. articles are not listed in the exhibits here, your 25 Q. At the bottom of Exhibit 10, the question 15

Page 302 Page 304 says: "Do FAW," forced-air warming blankets "increase correct? 1 1 the risk of SSI"; correct? 2 2 MS. ZIMMERMAN: Object to form. 3 A. Yes. 3 A. That is correct. 4 Q. On the next page is what the consensus 4 Q. For example, Albrecht -- Let me get you a copy, oh, even though this is my highlighting. statement is; right? 5 5 6 A. Yes. 6 MS. ZIMMERMAN: Counsel, if you're going to 7 Q. Will you read that? 7 show him a document I'm going to insist that we mark 8 A. "We recognize the theoretical risk posed by 8 it. If it's a document I have already that's FAW blankets and that no studies have shown an 9 unmarked I'd be happy to give it to you. MS. LEWIS: You said you have a clean copy? increase in SSI related to the use of these devices. 10 10 MS. ZIMMERMAN: Which one are you looking 11 11 We recommend further study but no change to current 12 practice." 12 at? 13 Q. What was the delegate vote with respect to 13 MS. LEWIS: This one is Albrecht 2011. 14 14 agree? (Discussion off the stenographic record.) MS. ZIMMERMAN: The 2010 Association For 15 A. Eighty-nine percent. 15 Q. Disagree? Professionals Infection Control Epidemiology? 16 16 A. Five percent. 17 17 Albrecht --Q. Abstain? 18 18 MS. LEWIS: No. Forced-air warming A. Six percent. 19 19 blowers. Q. And in the parenthetical what does it say? 20 20 MS. ZIMMERMAN: Yeah. Albrecht, Gauthier, 21 A. "Strong consensus." 21 Belani, et al? Q. So the consensus of that committee, based on 22 22 MS. LEWIS: Yeah. this document, was that they recognized the 23 23 MS. ZIMMERMAN: Here's one for the witness theoretical risk, but that no studies have shown an 24 and one for you. increase in SSI related to the use of these devices, 25 MS. LEWIS: Thank you. Page 303 Page 305 is that -- did I read that right? MS. ZIMMERMAN: They're both clean. 1 1 2 A. That is correct. 2 (Lampotang Exhibit 11 marked for 3 3 Q. You were asked questions about reasons why identification.) it was your opinion that several studies that you 4 4 BY MS. LEWIS: 5 talked about earlier; Albrecht, Reed, Belani, Dasari, 5 Q. Can you look on page 327, next-to-the-last 6 6 et cetera, did not show an increased risk of page? 7 7 infection, and two things you said were it was not a A. Okay. 8 clinical study, and that the authors acknowledged 8 Q. Okay. On the left-hand column, --9 limitations to the study. 9 A. Yes. 10 Do you recall that testimony? 10 Q. -- last paragraph, you see where it starts 11 "nevertheless"? 11 A. Yes. 12 Q. Can you --12 A. Yes. 13 Did those studies, let's start with 13 Q. Okay. Does it say there, our findings do Albrecht, for example. Did Albrecht make a statement not establish a direct link between FAW, forced-air 14 that it could not reach an -- a -- Did Albrecht -- and 15 warming, and increased SSI rates? 15 I'll -- I have the document in front of me if you want 16 A. In the last paragraph? 16 Q. Well it's -- the first -- the last to take a look at it. But did any of -- Let me ask 17 17 18 this question generally. 18 paragraph, it is the second sentence. Did any of the studies on which plaintiffs A. Yes. 19 19 20 rely, Albrecht, Legg, Belani, Dasari, Reed, Leaper, do 20 Q. Do you see that? any of those studies say that the Bair Hugger causes A. Yes. Yes. "Our findings do not establish a 21 21 direct link between FAW and increased SSI rates." 22 22 infection? 23 23 O. So Albrecht, it's --MS. ZIMMERMAN: Object to form. A. As far as I recall, they don't. 24 The study itself, the authors itself say 24 Q. In fact they say the opposite; is that 25 that their findings do not establish a direct link 25

between forced-air warming and increased SSI rates; correct? A. A. That is correct.  (Lampotang Exhibit 12 marked for identification.) (Discussion off the stenographic record.) BY MS. LEWIS: Q. It has my highlighting, doctor, sorry about that. But I'm going toI'm going to say I want you to read from page 8A, and what I want you to read surgical-site infections.  A. Thank you.  By MS. ZIMMERMAN: Object to form.  A. "the present study did not evaluate the link between forced-air warming and SSI rates"  In the between forced-air warming and SI rates, correct?  MS. ZIMMERMAN: Object to form.  A. "the present study did not evaluate the link between forced-air warming and SSI rates, correct?  MS. ZIMMERMAN: Thank you.  THE WITDEOGRAPHER: It's been 60 second with a warming and SSI rates, correct?  MS. LEWIS:  THE VIDEOGRAPHER: Can we go off the record identification.)  THE REPORTER: Off the record.  Chaptor as a verbaim shorthand rebesture of a forced-air warming and spar are unable to conclude that the use of the nature."  A. That's what it says.  Can you just read what it says in lightlighting?  THE VIDEOGRAPHER: Can we go off the record identification.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  THE REPORTER: Off the record.  Cheposition concluded at 4:50 p.m.)  The conclusion of the record.  Cheposition concluded at 4:50 p.m.)  The conclusion of the record		Dog 206		Page 308
2 correct? 3 A. That is correct. 4 (Lampotang Exhibit 12 marked for identification.) 5 identification. 6 (Discussion off the stenographic record.) 6 (Discussion off the stenographic record.) 7 BY MS. LEWIS: 8 Q. It has my highlighting, doctor, sorry about that. But I'm going to I'm going to say I want you to read is highlighed, and this is the Albrecht study of 2009. 10 to read from page 88, and what I want you to read is highlighed, and this is the Albrecht study of 2009. 11 A. Thank you. 12 A. Thank you. 13 Q. Can you just read what it says in highlighting? 14 highlighting? 15 MS. ZIMMERMAN: Object to form. 16 A. "the present study did not evaluate the link between forced-air warming and SSI rates.," and identification.) 17 If MS. ZIMMERMAN: Object to form. 18 Q. So in this Albrecht 2009 study the authors did not even evaluate any relationship between proced-air warming and SSI rates; correct? 10 forced-air warming and SSI rates; correct? 21 MS. ZIMMERMAN: Object to form. 22 A. That's what it says. 23 (Lampotang Exhibit 13 marked for identification.) 24 identification. 25 BY MS. LEWIS: How many more minutes? 26 for one second? 27 THE VIDEOGRAPHER: Can we go off the record. (Discussion off the record.) 28 BY MS. LEWIS: How many more minutes? 29 IT I'm Evipted a deposition, but as you know, allow me another maybe 60 seconds to finish my questioning? 10 Q. Okay. 11 A. Yes. 12 Q. Okay. 13 MS. LEWIS: I will be at 60 seconds, and you can stop me [to videographer]. 14 Q. Pere is one of the Legs studies. If you warming, awoul as accounted that the use of the forced-air grammar are unable to conclude that the use of the forced-air grammar are unable to conclude that the use of the forced-air grammar unable to conclude that the use of the forced-air grammar unable to conclude that the use of the forced-air grammar unable to conclude that the use of the forced-air grammar unable to conclude that the use of the forced-air grammar unable to conclude that the use of the forced-air grammar unable to conclude that the	1	Page 306  hotwoon forced air warming and increased SSI rates:	1	
A. That is correct.  (Lampotang Exhibit 12 marked for identification.)  (Discussion off the stenographic record.)  8 PYMS, LEWIS:  8 Q. It has my highlighting, doctor, sorry about or read from page 88, and what I want you to read is 11 highlighting.  12 A. Thank you.  13 Q. Can you just read what it says in 14 highlighting?  15 MS, ZIMMERMAN: Object to form.  16 A. "the present study did not evaluate the link between forced-air warming and SSI rates"  18 Q. So in this Albrecht 2009 study the authors did not even evaluate any relationship between 19 did not even evaluate any relationship between 20 forced-air warming and SSI rates; correct?  21 MS, ZIMMERMAN: Object to form.  22 A. That's what it says.  23 (Lampotang Exhibit 12 marked for identification.)  4 (Discussion off the stenographic record.)  5 the authors reached the conclusion that they could establish a causal relationship or an increased risk of the authors reached the conclusion that they could establish a causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of a dusting causal relationship or an increased risk of and surgical-site infections — beach gust				
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6 (Discussion off the stenographic record.) 7 BY MS. LEWIS: 8 Q. It has my highlighting, doctor, sorry about that. But I'm going to I'm going to say I want you to road from page 88, and what I want you to road from page 88, and what I want you to road from page 88, and what I want you to road from page 88, and what I want you to road from page 88, and what I want you to road is highlighted, and this is the Albrecht study of 2009. 12 A. Thank you. 13 Q. Can you just read what it says in lighlighting? 14 highlighting? 15 MS. ZIMMERMAN: Object to form. 16 In MS. ZIMMERMAN: Object to form. 17 In WINDESS: Thank you. 18 Q. So in this Albrecht 2009 study the authors of did not even evaluate any relationship between the Bair Hug and surgical-site infections between the Bair Hug and SIT ares 18 A. That is accorned that's what I've said throughout my deposition today.  The VIDEOGRAPHER: It's been 60 secord surgical steen forced-air and throughout my deposition today.  The WITNESS: Thank you.  MS. LEWIS: Okay. Thank you.  The WIDEOGRAPHER: Or the record.  (Discussion off the				
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9 that. But I'm going to I'm going to say I wanty you to read is 11 highlighted, and this is the Albrecht study of 2009. 12 A. Thank you. 13 Q. Can you just read what it says in 14 highlighting? 14 highlighting? 15 MS. ZIMMERMAN: Object to form. 16 A. "the present study did not evaluate the 17 link between forced-air warming and SSI rates" 18 Q. So in this Albrecht 2009 study the authors 19 did not even evaluate any relationship between 20 forced-air warming and SSI rates; correct? 21 MS. ZIMMERMAN: Object to form. 21 MS. ZIMMERMAN: Thanks. 19 did not even evaluate any relationship between 22 (Lampotang Exhibit 13 marked for 23 identification.) 24 dentification.) 25 MS. LEWIS: How many more minutes? 26 Q. D. Lampotang, we are sort of out of our 3 allow me another maybe 60 seconds to finish my 10 questioning? 27 Q. Okay. 28 MS. LEWIS: I will be at 60 seconds, and 20 you can stop me [to videographer]. 29 Q. Okay. 30 MS. LEWIS: I will be at 60 seconds, and 3 you can stop me [to videographer]. 31 A. "Because of the nature of the experiments we 3 are unable to conclude that the use of the forced-air you may none deposition today. 31 MS. LEWIS: Suen. 32 MS. LEWIS: A mark you. 33 MS. LEWIS: How many more minutes? 34 MS. LEWIS: How many more minutes? 35 MS. LEWIS: A mark you. 36 MS. ZIMMERMAN: Thanks. 36 MS. ZIMMERMAN: I'll just say that we we will also read the highlighting dia force and and sign. 37 MS. LEWIS: A marked for 20 MS. ZIMMERMAN: Thanks. 38 THE REPORTER: Off the record. 49 (Discussion off the record.) 40 Q. D. Lampotang, we are sort of out of our 3 allow me another maybe 60 seconds to finish my 30 questioning? 40 Q. Okay. 41 MS. LEWIS: I will be at 60 seconds, and 30 you can stop me [to videographer]. 41 A. "Because of the hatte use of the forced-air 31 page, please, which starts at "because of the nature." 14 page, please, which starts at "because of the nature." 15 page, please, which starts at "because of the nature." 17 page, please, which starts at "because of the nature." 18 are unable to co			7	
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12	10	to read from page 88, and what I want you to read is	10	A. That is correct, and that's what I've said
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24 between the Bair Hugger and surgical-site infections; 24				
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# CASE 0:15-md-02666-JNE-DTS Doc. 912-1 Filed 10/03/17 Page 80 of 260

# Confidential - Subject to Protective Order

Page 310	
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Date Signature of Witness  WITNESS MY HAND AND SEAL this day of, 2017.	
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# **EXHIBIT DX2**

TO DECLARATION OF BENJAMIN W. HULSE IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SAMSUN LAMPOTANG, PH.D.

Report of Samsun Lampotang, Ph.D.

In re Bair Hugger Forced Air Warming Products Liability Litigation, MDL No. 15-2666-JNE-FLN

#### **Background and Experience**

I am a Professor of Anesthesiology and an Affiliate Professor of Biomedical Engineering at the University of Florida (UF) and the founding Director of the UF Center for Safety, Simulation & Advanced Learning Technologies. I earned a PhD in Mechanical Engineering from the University of Florida in 1992, with a concentration in thermal sciences (heat transfer: conduction, convection and radiation, fluid mechanics, thermodynamics, mathematics). When studying heat transfer during my graduate studies, conduction, convection and radiation were considered as three separate and different heat transfer mechanisms with separate courses offered for each of these three distinct heat transfer processes. The specialized textbooks recommended for each of the specific courses guide engineering students in understanding the fundamentally different governing equations that describe these three inherently different processes of heat transfer.

The overarching goal of my research is patient safety that I address through (a) better hands-on clinician training through simulation and (b) making existing devices better. For my doctoral dissertation, I designed, built and evaluated an electronically-controlled anesthesia machine. I have worked on a daily basis in an anesthesia environment for 35 years. I teach UF anesthesia residents (since 1992) and practicing anesthesiologists how to safely use anesthesia machines at invited international lectures and since 2007 during hands-on anesthesia machine workshops at the American Society of Anesthesiologists (ASA) annual meeting. As part of a week-long anesthesia course to executives and engineers of anesthesia corporations/entities, I have taught FDA engineers using simulators I have designed and invented. I accepted the ASA president's invitation to serve another three-year term on the Equipment & Facilities Committee, and am on the Committees on Technology and the Committee on Education & Training of the Anesthesia Patient Safety Foundation. I am a member of the Advisory Group of the World Federation of Societies of Anaesthesiologists (WFSA) and of the Anesthesiology Performance Improvement Committee (APIC) of the University of Florida, Department of Anesthesiology. I am also an invited member of the ASA ad hoc committee for Advanced Technology and Training Planning Committee designing the course "Safe and Effective Use of Anesthesia Machines". I designed two of eight sections: "Pre-use check" and "Troubleshooting." I obtained formal training as a simulation instructor at the Harvard Center for Medical Simulation and teach a day-long simulation-based course to practicing anesthesiologists (8-10 per course) needing Part IV of the American Board of Anesthesiology (ABA) Maintenance of Certification in Anesthesiology (MOCA).

My work as a researcher and engineer based in a clinical department is at the intersection of anesthesia and engineering: it includes infection prevention (skin prepping, prophylactic antibiotic dosing and timing, EVD catheter tunneling training materials; urine drainage systems), temperature management (co-inventor on microwave blood/fluid warmer patent to help maintain normothermia; co-inventor on cooling football pads patent that has been

commercialized for heat stroke prevention; Peltier heat exchanger for use during anesthesia; a novel closed circuit anesthesia machine that preserves heat and humidity) and study design (including clinical studies). I have obtained grants a) from the manufacturer to design and build a skin prepping screen-based simulator for the ChloraPrep applicator that is used to train clinicians, b) from the manufacturer to study heat and moisture exchanger performance, c) from the National Football League to study the efficacy of temperature management via aircooled football pads, and d) to evaluate the usability (simulator-based study) of working models of anesthesia equipment from multinationals prior to FDA approval. Other screen-based simulators I have designed include a screen-based simulation of the pharmacokinetics and pharmacodynamics of cefazolin (Ancef), an antibiotic that is administered prophylactically (to prevent SSI) before surgical incision and is subsequently re-dosed during prolonged surgery. We include the timing and dose of prophylactic cefazolin administration in our MOCA sessions because we have noted some confusion about proper dose and timing, among anesthesiologists who administer the cefazolin when we discuss the topic during our MOCA sessions. I am a co-investigator on a submitted translational proposal to train patients to ask clinicians to wash their hands to prevent hospital-acquired infection as recommended by the Centers for Disease Control and Prevention (CDC) and evaluate the effect of the training on behavior and patient outcomes.

I am a designer and inventor of multiple anesthesia-related products including: (a) the Hamilton Max commercial transport ventilator which emphasized usability, (b) a multi-vented urinary drainage system to reduce catheter-associated urinary tract infection, recently licensed by the University of Florida to industry, (c) the CAE/METI Human Patient Simulator, a commercial mannequin simulator analogous to a flight simulator for patients, (d) the Virtual Anesthesia Machine online simulation portfolio and web site (44,000 registered users worldwide, in 23 languages and 6 medical gas color codes), (e) a mobile device-based simulation for learning skin disinfection with the ChloraPrep, a chlorhexidine-based applicator, (f) an industry-funded panoramic simulation to learn and practice neuromuscular blockade administration, monitoring, and reversal and (g) five DoD-funded simulators for military medical personnel and reservists to practice procedural skills and aseptic techniques while deployed in austere environments. I am a named co-inventor on 40 issued US patents; one of the latest ("Materials and methods for maintaining proper body temperature") is used by high school, college and NFL football teams as well as in other sports. The full description of my body of work is in my CV, hereby incorporated into this report as Exhibit A.

I was the principal investigator on a research grant awarded to our simulation lab by CareFusion, the manufacturer of the ChloraPrep (2% chlorhexidine glugonate, 70% isopropyl alcohol) skin preparation applicator, to design and build the simulator mentioned in (e) above. We designed a screen-based simulator to explicitly address specific learning objectives that must be mastered to properly use the applicator to its full capability and to provide an engaging means for users to unlearn deeply ingrained skin prep techniques that they may have been using for decades. Among the numerous learning objectives we imbedded in the simulator, one is to use a "to and fro" pattern instead of the traditional expanding spiral pattern to obtain better application of the disinfectant. Another learning objective is to scrub for at least 30

seconds with the applicator to exfoliate dead skin cells and reach any colony forming units (CFUs) beneath them. The "to and fro" motion is illustrated at <a href="https://www.youtube.com/watch?v=UAiTfPiHYXc">https://www.youtube.com/watch?v=UAiTfPiHYXc</a>. Note that the CareFusion ChloraPrep video shows one organism remaining at the end of proper skin prepping during incision.

As part of my 35 years of research, teaching, and work in the anesthesia environment, I am very familiar with patient temperature management devices, including forced air warming devices such as the Bair Hugger. The University of Florida Academic Health Center uses the Bair Hugger

I was asked by Blackwell Burke P.A. to review expert reports, depositions and other materials concerning the use of forced air warming devices such as the Bair Hugger during surgery and any associated risks of surgical site infections (SSI). I am compensated at a rate of \$500 per hour for my time in reviewing materials and preparing this report, \$500 per hour for deposition testimony, and \$500 per hour for court testimony.

In the past four years, I have provided court and/or deposition testimony for the following cases:

Becky S. Anderson v. Medtronic, Inc. et al., Washington Superior Court, County of King, No. 12-2-17928-0 SEA.

Ramirez v. Rush Copley Medical Center, In the Circuit Court of Cook County, Illinois County Department, Law Division No. 09 L 13262(D)

device.

#### **Materials Reviewed**

In drafting this report, I have considered the materials referenced in Exhibit B.

I may use all or parts of the materials referenced herein, or summaries and depictions thereof, as exhibits or demonstrative aids to summarize or support my opinions.

#### **Opinions**

#### 1. The Bair Hugger Warming Unit is a Safe and Efficacious Medical Device

The Bair Hugger is a forced air warming device; it is a reasonable, safe, easy to use and efficacious device. I disagree with Plaintiffs' assertion that the design and labeling of the Bair Hugger are defective. The Bair Hugger (BH) has a proven track record of keeping a multitude of patients warm intraoperatively and is within industry standards. The Bair Hugger design is appropriate and reasonable for the intended purpose of the Bair Hugger.

The known benefits of normothermia such as a <u>reduction</u> in incidence of post-operative infection and adverse myocardial events and decrease in length of stay at the hospital are well-

established and, in fact, recommended and required. Recently (May 2017), the Centers for Disease Control and Prevention (CDC) issued updated guidelines in JAMA that reaffirmed the importance of maintaining intraoperative normothermia, a function that the widely-used Bair Hugger accomplishes well. The Surgical Care Improvement Project (SCIP) metric SCIP-Inf-10 is sponsored by the Centers for Medicare and Medicaid Services – CMS, in collaboration with other national entities such as the Centers for Disease Control and Prevention and the Institute for Healthcare Improvement. It is another example of the recommendations for intraoperative normothermia. A metric of SCIP-Inf-10 is at least one temperature reading 36°C or higher within 30 minutes before or 15 minutes immediately after anesthesia end time. For short time duration anesthesia cases, the rate of warming or rewarming of patients is an important performance indicator for an active warming device because the time window to achieve the temperature target is shrunk.

By this metric, the Bair Hugger has been shown to safely maintain normothermia more effectively than alternative modalities. As an example, the Bair Hugger was demonstrated to provide twice the rate of patient temperature increase compared to the Hot Dog conductive device<sup>i</sup>, a consideration that is important for short duration anesthesia cases. Other warming modalities may have risks not present in forced-air warming.

# 2. Arizant and 3M Acted Reasonably in Designing, Developing, and Marketing the Bair Hugger

I have reviewed the design and development history file as well as the 510(k) file for the Bair Hugger Models 505, 750, and 775, as well as other documents related to the design and testing of the Bair Hugger. In my opinion, Arizant/3M, and their employees and agents, acted reasonably, prudently, and within industry standards in the design, testing, evaluation and development of the Bair Hugger.

The design, testing, and risk management documents for the Bair Hugger indicate reasonable and prudent care in the development of a safe and efficacious device and incorporation of appropriate risk mitigation measures to identified risks. For example, the Model 750 510(k) submission considers the possible safety concern of airborne contamination and includes appropriate mitigations.

I have reviewed tests of the Bair Hugger filter media that indicate that it meets MERV 14 at a flowrate of 48 cfm in accordance to ASHRAE Standard 52.2-2012 and Addenda a, b, and d to Standard 201, 2015 Supplement. The filter media for the Bair Hugger models have the same Minimum Efficiency Reporting Value (MERV) 14 rating that is acceptable for general surgery.

The Bair Hugger's warnings and labeling are adequate, easily understood, and provide instructions for taping the Bair Hugger blanket to the patient. An adhesive strip at the edge of the Bair Hugger warming blanket is used to tape the blanket to the patient and prevent air from being directed to the surgical site. The warnings and labeling reasonably do not include a warning regarding a risk of infection, because there is no valid evidence of such an alleged risk

(as discussed below). In addition to the tape strip, the sterile drapes that are hung between IV poles near the patient's head form a barrier to air flow towards the surgical wound.

Arizant/3M's decision to consider but not implement potential design changes, such as the addition of a hose end filter, was reasonable, as such changes would have altered the usability (noise level, form factor) and efficacy (reduction of the flowrate of warmed gas delivered to the blanket resulting in reduced efficacy in establishing and maintaining normothermia) of the device, and were unnecessary given the lack of evidence that the Bair Hugger causes infections. It was also reasonable to not incorporate a HEPA filter for the same reasons: reduced normothermia efficacy because the higher pressure drop across a HEPA filter reduces air flow rate out of the blanket which in turn reduces convective heat transfer.

It is my opinion that Arizant/3M took the high road and acted with poise and restraint in its official response to allegations about its forced air warming technology, sticking to the science and the facts, and undertaking additional testing of the Bair Hugger. I am not aware of any misrepresentations of the safety of the Bair Hugger or forced air warming by Arizant/3M or any of its employees.

In my opinion, Arizant/3M acted transparently and appropriately in sponsoring outside independent research related to forced air warming. As an academic researcher and a recipient of industry-sponsored research that has been disseminated as a peer-reviewed publication, I personally know first-hand that academic institutions have long had safeguards and rules to ensure that industry-sponsored research is truly independent, irrespective of the results of the sponsored research and that funding from industry does not exert undue influence on the outcomes of the study. There are also strict disclosure rules, especially in medicine, that require disclosure of any potential Conflict of Interest by the authors.

## 3. The Bair Hugger Does Not Contaminate the Surgical Field

There is no evidence that the Bair Hugger, including its filter, is inadequate, defective, or causes infections. In one study, samples of air exiting Bair Hugger blankets did not culture any organisms. Bernards et aliii were able to identify during an actual infection outbreak Acinetobacter baumannii (AB), the infectious organism, in the Bair Hugger filter, indicating that the Bair Hugger filter effectively trapped AB during an actual clinical outbreak in real world conditions, with real patients, personnel and machines in actual patient care areas, and importantly not in studies using surrogates like bubbles, simulation ORs or unvalidated mathematical models with debatable assumptions.

# 4. Real World Data From an Actual Infection Outbreak: Bair Hugger Filter is Effective at Trapping Acinetobacter Baumannii

Acinetobacter baumannii (AB) is rod shaped and has a size of 0.9 - 1.6 micrometers by 1.5 - 2.5 micrometers.

https://catalog.hardydiagnostics.com/cp\_prod/Content/hugo/Acinetobacter.htm. During an

actual outbreak of AB in the Netherlands (Bernards et al. 2004), AB was identified in the Bair Hugger filter. The authors specified three interventions that stopped the AB outbreak: 1) cleaning dust where AB had been identified from inside a respirator, 2) cleaning dust from inside a CVVH machine where AB had been identified, and 3) changing the Bair Hugger filter on which AB had been identified. The authors did NOT specify that the interior of the Bair Hugger was cleaned apart from changing its filter, contrary to what could be misconstrued from other summaries of Bernards' paper that I have reviewed.

I have carefully reviewed the Bernards paper. The description of the Bernards study on page 27 of David's report is incorrect and misleading. "After cleaning and filter replacement, the outbreak stopped." (emphasis added) The previous sentence will likely be misconstrued to mean that the Bair Hugger was cleaned. Similarly the Jarvis report (page 12) writes: "After the removal of the dust and replacement of the filters of the Bair Hugger FAW, the first outbreak was stopped". This statement too will be misconstrued as dust being removed from the BH. In fact, the dust was removed from respiratory ventilators and CVVH machines - relevant information that Jarvis does not mention when summarizing the Bernards paper - and that the respirator and CVVH dust were identified as containing AB. The authors only indicate that the Bair Hugger filter was changed and did not mention that the Bair Hugger was cleaned (I do not consider changing the Bair Hugger filter as cleaning the Bair Hugger). On the other hand, the authors specifically mention that accumulated dust inside the ventilator and CVVH machines were cleaned. Given that there is no specific mention of cleaning the Bair Hugger (unlike specific mention of cleaning the ventilator and CVVH machines), we can assume that the Bair Hugger was not cleaned. Given that the outbreak stopped, even though the Bair Hugger interior was not cleaned and only the Bair Hugger filter was changed, this indicates that the interior of the Bair Hugger was not harboring the infectious organism Acinetobacter baumannii that was causing the outbreak. Had the Bair Hugger filter allowed the AB to pass through, then the interior surface of the Bair Hugger downstream of the filter would have harbored AB just like the ventilator and CVVH did. Simply changing the Bair Hugger BH filter would not have stopped the outbreak if the Bair Hugger interior downstream of the filter was harboring AB. The fact that the outbreak was contained after changing the Bair Hugger filter without cleaning the Bair Hugger interior indicates that the existing filter did its job and did not allow AB to pass downstream of the filter. It also means that the AB found on the Bair Hugger filter was on the upstream side of the filter indicating that the AB was trapped by the filter and most likely came from the dust in the electronics and the interior of the respirator and CVVH machine.

## 5. There is No Indication that Surgical Site Infections are Caused by the Bair Hugger

I disagree with the opinions of Plaintiffs' experts that the Bair Hugger is a significant factor in the increased risk or cause of surgical site infections. Based on the available, credible scientific literature, there is no evidence that the Bair Hugger causes, or is a significant factor in causing surgical site infections (Avidan, Huang, Moretti, Zink). Likewise, there is no evidence that the Bair Hugger increases the risk of surgical site infections. No studies have shown that forced air warming causes infection or should not be used to maintain normothermia in patients. The

theoretical concerns of the plaintiffs and their experts regarding potential disruption of laminar air flow are based on questionable studies<sup>iv</sup>, not clinical evidence. There are also other causes of laminar flow disruption such as boom arms or the heads and upper bodies of OR personnel. Further, the efficacy of laminar flow has been questioned. Multiple studies, on the other hand, have shown that forced air warming does not contaminate the surgical site.<sup>v,vi</sup> No studies have demonstrated a causal relationship between the Bair Hugger and a surgical site infection.

There are studies (some using surrogates like bubbles for infectious organisms) and mathematical models that have been produced, but no study has proven a direct cause and effect chain. Causality is not an unattainable or unreasonable bar. Causality can be established as Bernards et al (2004) did in the case of outbreaks of Acinetobacter baumannii. Studies such as Birgand 2015<sup>vii</sup> conclude by suggesting further studies are needed because the evidence is inconclusive.

Also at <a href="https://www.cdc.gov/hai/pdfs/stateplans/factsheets/us.pdf">https://www.cdc.gov/hai/pdfs/stateplans/factsheets/us.pdf</a>, the CDC reports that SSIs have had a significant decrease of 17% in the US. Had the Bair Hugger been the cause of SSIs as alleged by plaintiffs and given its continued widespread use, the expectation is that SSIs should have increased, not decreased.

#### 6. Numerous Potential Causes/Risk Factors of Surgical Site Infections

There are numerous potential causes and risk factors of SSIs. I base my opinion on several grounds, including, but not limited to:

- It is hard to achieve complete sterilization. That may explain why, in spite of best efforts and processes, infections unfortunately still happen. Using the ChloraPrep as it is intended to be used will help to obtain maximum log reduction in CFUs. One log reduction means reducing the amount of bacteria by 90% so that 10% remain, 4 log reduction is a 10<sup>4</sup> (10 to the power of 4) reduction so that 1,000,000 CFUs are reduced to 100 CFUs (99.99% kill) - see https://www.ciriscience.org/a 107-What-is-Log-Reduction. According to the CareFusion web page at http://www.carefusion.co.uk/pdf/Infection Prevention/Product Characteristics Clear.p df the log reduction of ChloraPrep is >4 and < 6 depending on the organism. This log reduction range means that if there are one million CFUs initially, there is a non-zero probability that there will be one CFU left after PROPER use of ChloraPrep. For example, with a log reduction of 5, there will be ten CFUs left from an initial 1,000,000. The ChloraPrep applicator was likely used for some of the MDL cases; the manufacturer's data indicate that the possibility of one CFU from the patient's skin surviving after skin preparation cannot be excluded. 100% effectiveness or sterility is hard to attain including in skin prepping. Layers of defense against infection such as prophylactic antibiotics can help while predisposing risk factors do not.
- It is unclear whether the proper chlorhexidine applicator scrubbing pattern (to and fro or back and forth) would have been used instead of the more common, but no longer recommended, spiral pattern expanding from the proposed incision site. It is also

- unclear if the skin would have been scrubbed for at least 30 seconds with the chlorhexidine gluconate applicator. Log reduction of CFUs will be sub-optimal if the "to and fro" pattern was not used and/or scrubbing was done for less than 30 seconds, among other potential lapses in technique.
- To provide multiple defenses against infection instead of relying on just one, the latest May 2017 CDC Guidelines recommend "8A.1. Advise patients to shower or bathe (full body) with soap (antimicrobial or nonantimicrobial) or an antiseptic agent on at least the night before the operative day. (Category IB-strong recommendation; accepted practice.)" Failure of patients to comply with this recommendation is difficult to monitor without intruding on their privacy. Failure to follow this recommendation leaves a larger number of organisms on the patient's skin that can increase the risk of surgical site infection if the majority of infectious organisms on and around the incision site are not significantly reduced during skin prepping.
- Increased tissue oxygen delivery is recommended for prevention of SSI in the CDC 2017 Guideline.
- Prolonged surgery, unforeseen complications and delays that prolong the time interval from prophylactic antibiotic administration to surgical incision can push the surgery past the recommended time interval for prophylactic antibiotic (Ancef) redosing.
- Pre-existing diabetes is a well-known surgical infection risk.
- Prophylactic antibiotics must be properly adjusted for patient weight.
- There are multiple areas in the OR but outside the sterile area that are not sterile.
   Multiple sources of bacteria exist in an OR including on the anesthesia machine controls (Loftus et al. 2011, Munoz-Price et al. 2013).
- Clutter/obstructions above the patient. X-rays are sometimes obtained during surgery. The introduction of an X-ray machine of undetermined/undocumented disinfection in the sterile field is yet another potential source of bacteria. Depending on the radiograph being taken, parts of the X-ray machine may be positioned above the patient or the surgical incision. Boom arms are also used to allow ceiling-hung equipment to be readily positioned where they are needed and swung out of the way when not needed. At a minimum, the boom arms interfere with air flow from the ceiling and in a worst case scenario, the top surfaces of the boom arms will be dusty if not cleaned regularly.

## 7. Sources of dust, heat and gas outflows in OR

There are multiple sources of gas, beyond a forced air warming blanket, in the operating room including but not limited to those listed below. Many of those gas sources do not have their internal flow passages conveniently accessible for cleaning. In some cases, the air blown into the operating room's ambient environment may also contain infectious organisms or droplets from the patient's respiratory system.

a. Numerous devices in an OR such as physiological monitors, the anesthesia machine, X-ray machines, CVVH machines, OR computers, ceiling-hung display monitors, etc. use electronics that require cooling and blow out the resulting heated air into the OR's

- ambient environment. Accumulated dust inside the electronics and interior of the equipment can contain bacteria.
- b. The drive gas in some anesthesia machine bellows ventilator exhaust oxygen directly into the OR ambient environment at about head level as demonstrated in the Virtual Anesthesia Machine screen-based simulation. The drive gas outflow is approximately equivalent to the minute ventilation and for an adult can range from 7-10 liters/minute or more. If the bellows that separates circuit gas (gas in contact with the patient's lungs and the internal plumbing in the anesthesia machine) from drive gas (gas squeezing the bellows during inspiration) leaks, then drive gas and circuit gas will mix and circuit gas (containing any infectious organism from the patient's respiratory system) can escape along the outflow path for the drive gas into the OR (Lampotang et al.)<sup>x</sup> at eye level.
- c. In the case of an incorrectly set anesthesia machine scavenging system, gases from the breathing circuit exhaust into the room at about knee level without any warning that the scavenging system has failed. Gases spilling out of a malfunctioning or improperly adjusted scavenging system is a source of unsterile gas outflow into the OR. If the patient has respiratory infection, the gas coming out of the breathing circuit has been in contact with the patient's lungs and can carry infectious organisms that are released into the room if the scavenging system fails. Gases exhaled by the patient into the scavenging system are generally warmer that room air because some have been in contact with the patient's lungs and will definitely be warmer if a heater/humidifier is being used in the anesthesia breathing circuit as is done in long duration cases.
- d. Anesthesia breathing circuits, including the bellows, are known to leak. Just like with a scavenging system leak, a leak from the anesthesia breathing circuit introduces unsterile gas into the OR.
- e. Other sources that spill gas into the OR ambient environment are cuffless endotracheal tubes, ill-fitting cuffed endotracheal tubes, supraglottic devices, or facemasks and open systems such as nasal cannulae, among others.
- f. Smoke from surgical cautery is another gas source and has raised concerns about the safety and the potential risk of infection of surgical personnel exposed to it.

There are multiple sources of heat, beyond a forced air warming blanket, in the operating room including but not limited to high intensity surgical lights and endoscopic lights and various electronic equipment. In one study employing computational fluid dynamics and particle-tracking methodology, the total heat emission from these sources, as well as the patient, accounted for more than four times the 500 watts heat dissipation from a forced air warming device. This study found that with the forced air warmer on or off there was zero percent deposition of contaminant sources on the patient. The large amount of heat generated by high intensity lights requires a higher flow rate of cooling air to dissipate the heat to keep the equipment cool and functioning properly.

A positive pressure OR can be used for infection control instead of a laminar flow system. Failure of the positive pressure OR system is not a rare occurrence. It is unclear whether the positive pressure system, if present, would have been working properly during the MDL cases. The possibility that the positive pressure system was malfunctioning and might have caused the

infection cannot be ruled out. There is usually no alarm when the positive pressure system fails. OR personnel are often unaware of the tell-tale that allows them to visually check if positive pressure is being maintained inside the OR. Even if OR personnel are aware, it is easy to forget to check the tell-tale or not notice that it is indicating a malfunction because it is usually placed above the door and is therefore usually out of the usual line of sight ("out of sight, out of mind") of OR personnel in the sense that they would have to consciously remember to look up.

Movement/traffic in and out of an OR with opening and closing of doors leading to increased airflow and turbulence can be a factor in increasing particle counts. It is unclear how much traffic occurred during the MDL cases.

#### 8. Latest CDC Guidelines

Further support that there is no evidence of forced air warming causing surgical site infection is provided by a recent JAMA May 2017 paper that describes the Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017 (Berrios-Torres et al. 2017)<sup>Xiii</sup>. In fact, the 2017 CDC Prevention of SSI Guideline recommends "Maintain perioperative normothermia", an indication that forced air warming devices such as the Bair Hugger are widely used and considered effective in maintaining normothermia. The 2017 CDC guidelines provide new and updated evidence-based recommendations for the prevention of SSI based on a targeted systematic review of the literature conducted in MEDLINE, EMBASE, CINAHL and the Cochrane Library from 1998 through April 2014. Of note are:

- (a) the recommendation to "Maintain perioperative normothermia" which is categorized with the highest level of evidence-based recommendation: 1A. Forced air warming such as provided by the Bair Hugger is a means of maintaining perioperative normothermia; as such, the latest CDC guidelines reaffirm the patient safety contribution of the Bair Hugger in establishing and maintaining normothermia.
- (b) the absence of recommendations against forced air warming as a cause of SSI
- (c) other factors (but not FAW) that the CDC includes in its guidelines as potential causes of SSIs that should also be considered for the MDL
- (d) the guidelines document was published in May 2017 in the Journal of the American Medical Association (JAMA) and represents the latest and most current position of the CDC and infection experts on SSIs.

#### 9. Alternative Designs

Maintaining normothermia (recommended by the latest CDC SSI Prevention Guideline) is an intended function of the Bair Hugger. The ability to establish and maintain normothermia is dependent on the outflow rate of warmed air from the Bair Hugger blanket. A higher outflow

of warm air from the Bair Hugger blanket provides a higher convective heat transfer rate to patients facilitating quicker warming or rewarming. Filters that can trap smaller particles will in general have higher flow resistance and therefore a larger pressure drop across them. This in turn leads to a lower outflow from the Bair Hugger blanket as a result of using a filter that can capture smaller particles. There is therefore a trade-off between filter selection and outflow of warm air (normothermia efficacy) from the Bair Hugger blanket. A HEPA filter (99.97% efficient on particles of 0.3 microns in size) has been mentioned. A HEPA filter will degrade outflow and thus normothermia efficacy compared to the filter selected for the Bair Hugger. Real world results from the field in an actual outbreak of Acinetobacter baumannii suggest that the current filter selected for the Bair Hugger was effective in trapping the infectious organism while having an acceptable pressure drop across the filter that does not significantly degrade the outflow from the blanket, and thus normothermia efficacy.

The David report mentions the Mistral convective forced air warming system that uses HEPA filters: "a HEPA filter would help mitigate some of the risk by preventing the warming unit from collecting and incubating bacteria of its own." First of all, the "risk" is theoretical. The AB outbreak reported by Bernards supports that the Bair Hugger filter does what it was intended to do and may not need to be unnecessarily upgraded to HEPA performance at the potential cost of reduced normothermia efficacy. The AB outbreak and its resolution also strongly suggest with real world evidence that the Bair Hugger filter was effective in "preventing the warming unit from collecting and incubating bacteria of its own." Even a HEPA filter can fail, as Crowder (the corporate representative of the Bair Hugger filter manufacturer, Pentair) asserted during his deposition (p 55): "

- Q: .... would you agree with me that a -- that a HEPA filter is, for all intents and purposes, 100 percent effective at filtering out one-to-three-micron particles?
- A. I would say that it is highly efficient, it is very good at removing; I would not use the phrase "100 percent."

  O. Okay.
- A. It's not something we would use in relation to our medical filters.

The Warm Touch forced air warming device uses a HEPA filter. Avidan showed that the presence of the HEPA filter in the Warm Touch did not prevent S. Epidermis and Aspergillus Fumigatus from being cultured in the outflow from the Warm Touch that did not flow first through the warming blanket. The fact that the Warm Touch, equipped with a HEPA filter, generated air outflow from which organisms were cultured indicates that a HEPA filter is not a magic bullet. The speculation that adding a HEPA filter will improve the safety of the Bair Hugger is unproven and as discussed may even be detrimental in terms of normothermia efficacy.

The TableGard has been mentioned as an alternative to the Bair Hugger. TableGard is a product to prevent intraoperative development of pressure sores using alternating pressure

redistribution among air cells in a mattress. TableGard uses conductive technology, not convective technology and as such is not an alternative design to the Bair Hugger because it is a different product using a different heat transfer mechanism: conduction instead of convection. Focusing on the flow rate of warmed air out of the blanket and onto the patient, the TableGard cannot be "as effective as the Bair Hugger" — as asserted in the David report on page 40 — because a reduction in flow rate results in a decrease in heat transfer from the blanket to the patient. The flow rate of warmed air out of the blanket and onto the patient in the TableGard is the lowest value it can be at zero, meaning that there is zero convective heat transfer.

VitaHeat has been mentioned as an alternative to the Bair Hugger. VitaHeat is essentially an electric heating blanket that uses conductive technology, not convective technology and as such is not an alternative design to the Bair Hugger because it is a different product using a different heat transfer mechanism: conduction instead of convection.

Silver coating also is not a magic bullet. It did not live up to its promise in dwelling urinary catheters and urine drainage systems. The rate of catheter associated urinary tract infections (CAUTI) did not decrease when silver coating was used. As far as I am aware, the David report did not identify a device with silver coating on internal surfaces. What works in the lab in controlled conditions may not work in the real world. Silver coating, if implemented, may end up adding expense without benefit.

The WarmAir is a convective forced air warming device. It has an airflow of 35 cfm versus 48 cfm for the Bair Hugger (Wagner et al. 2008)<sup>xiv</sup>.

The David report states (page 43): "However, the most prudent option is to avoid all air-circulating devices." Any equipment (including electronic ones like computers, monitors, physiological monitors, anesthesia machines, ventilators and CVVH machines) that requires a cooling fan to prevent internal overheating is an air-circulating device. The outflow of air generated by the cooling fan blows heat and dust (and in the outbreak reported by Bernards, Acinetobacter Baumannii) away from the equipment and into the OR. An AB outbreak stopped when previously unsuspected equipment that were likely not appreciated as air circulating devices were found to harbor AB and were subsequently cleaned. Bernards reports that AB was identified in the Bair Hugger filter indicating that the Bair Hugger filter trapped the AB. The recommendation in the David report to "avoid all air-circulating devices" would essentially mean that all equipment with a cooling fan would be removed from the OR, leaving a poorly equipped OR that would present a safety hazard to the patient. Air circulating devices such as HCUs, CVVH and respirators may not have the intake filter that the Bair Hugger has such that any infectious dust can flow unimpeded to the ambient air in the OR.

## 10. Do Not Blow Air in the OR – Implications

The CDC DRAFT HICPAC Meeting Minutes, November 5-6, 2015 included this sentence that has been quoted in other reports such as David's and Jarvis's: "Nothing that blows air should be in an operating theater, if possible." This sweeping statement taken literally would imply that the

HVAC system, which blows air, should also not be in an OR. A close review of the HICPAC minutes informs us that this sentence was referring to infection resulting from cooling air circulated by a heater cooler unit (HCU). Unlike the Bair Hugger, the HCU uses water; the HICPAC minutes include this text: "In looking inside the machine, it is clear that a reservoir of warm water in a steel container in a chilled operating theater will have condensation that will drip. The insulation layered inside the machine is a non-cleanable foam. The situation is perfect for growing all manner of organisms.... The large cooling fan at the base of the device and louvers on the side of the machine contribute to chaotic dispersal of potentially contaminated air. ... There may be concerns associated with the smaller cooling fan that blows air out of the device because it is closer to tables that may hold sterile equipment." There is no water in the Bair Hugger and it is not designed to be used with water unlike the HCU. In fact, when water was accidentally introduced into a Bair Hugger, there was a fire. The clear differences in function and design (including the use of water in the HCU) between the Bair Hugger and the HCU show that there is no basis to assert that the HCU is similar to the Bair Hugger.

Water promotes survival of infectious organisms. The absence of water in the Bair Hugger design (unlike in the HCU) helps mitigate the risk of harboring infectious organisms inside the Bair Hugger. Bacteria also live in water droplets. As Crowder testified (page 52) in terms of removal of bacteria, "My understanding is that bacteria, in order to survive, needs to be in water, needs to be kept wet, so my experience with testing for removal of bacteria in airflows has been to remove droplets of -- of water with bacteria in them." This is consistent with Albrecht 2011<sup>xv</sup> where respiratory droplets are listed among the common forms of "particulate matter suspended in the operating room (OR) air." Droplets of water generally range in diameter from very fine (<60 microns) to ultra coarse (>650 microns) to drops of 4 mm (4,000 microns) and are thus larger than the bacteria they may host which in turn may have an impact on the effective size of bacteria (residing in the droplets) that a filter can trap.

# 11. Fire in the Bair Hugger (As described in 2017 Moon et al., Forced air warming device failure resulting in smoke and soot on a surgical patient).

The fire inside a Bair Hugger unit (at the blower motor downstream of the air intake filter) where soot generated by the fire (combustion) was not trapped by the pores in the Bair Hugger warming blanket has been mentioned in multiple expert reports as an indication that the Bair Hugger blanket does not trap infectious organisms. (Moon et al. 2017)<sup>xvi</sup>

Table 8 (MERV Efficiency Parameters) on page 12 of the Koenigshofer report states that combustion smoke is < 0.3 microns and that most smoke is 0.3 - 1 micron.

Narrowing down the <0.3 micron size range for combustion smoke, if we assume that the soot formed from the Bair Hugger fire is similar in size to Diesel Particulate Matter (DPM) <a href="https://www.dieselnet.com/tech/dpm\_size.php">https://www.dieselnet.com/tech/dpm\_size.php</a>, then it would be 0.01 to 0.1 micron (micrometer) in size, 90 to 9 TIMES smaller than the smallest dimension (0.9 micron) of, e.g., Acinetobacter Baumannii (AB; rod shaped with a size of 0.9 - 1.6 micrometers by 1.5 - 2.5

micrometers. HEPA filtration – which removes at least 99.97% of 0.3 micron-sized particles (30 times larger than 0.01 micron soot) at the rated flow in accordance with IEST-RP-CC001.3 – would have allowed DPM (0.01 micron soot) to go through it.

From a scientific basis, alleging that the presence of soot on the patient's skin when there was a Bair Hugger fire indicates that the Bair Hugger BLANKET does not trap infectious organisms is weakened by the much smaller size of soot compared to the size and mass (inertia; Crowder deposition) of infectious organisms like AB. To put this in layman's perspective, a ninefold difference (let alone a 90 fold difference) in diameter is larger than even the difference between a basketball (9.4") and a ping pong ball (1.6"). Simply stated as an analogy, that ping pong balls went through does not imply that basketballs will also pass through. http://www.topendsports.com/resources/equipment-ball-size.htm

Furthermore, Avidan demonstrated that the warming blanket was effective in trapping organisms: organisms that were cultured when the outflow of Bair Hugger was sampled without flowing through the blanket were not present when the outflow was sampled after flowing through the Bair Hugger warming blanket.

#### Conclusion

It is my opinion that the Bair Hugger is a safe and efficacious medical device. It is my opinion that the Bair Hugger was not defectively designed, tested, labeled, or manufactured and that Defendants acted reasonably and within industry standards related to the design, testing, analysis, research, and development of the Bair Hugger Models 775, 750 and 505. Based on available, credible, scientific literature, there is no evidence that the design of the Bair Hugger causes or increases the risk of surgical site infections or is a substantial factor in causing or increasing the risk of SSIs.

Based on available data including actual infection outbreaks where the source of infection was identified (Bernards, HCU), there is no evidence that the Bair Hugger, nor any alleged actions or inactions of Defendants, causes or increases the risk of surgical site infections. The data supporting this conclusion include: (a) the BH filter was effective in trapping AB in an actual outbreak in real world conditions (Bernards), (b) there is no report that I am aware of such as Bernards or the HCU where the Bair Hugger is documented to have caused an infection; (c) HEPA filtration did not prevent Avidan from culturing organisms from a Warm Touch; absence of HEPA filtration does not necessarily make a design less safe, (d) the BH blanket acts as an additional filter as reported by Avidan and (e) some studies that have raised concerns about the BH have used surrogates such as bubbles or mathematical models; the validity of these surrogates or models depends on the assumptions and simplifications made.

The opinions in this report are given to a reasonable degree of engineering and scientific certainty. They are based upon my education, training, experience, as well as the above list of materials reviewed.

This report is not meant to be an exhaustive recitation of all of my opinions. I reserve the right to amend and supplement the opinions expressed in this report. I also reserve the right to respond to and rebut all information provided in discovery, which I understand is ongoing, specifically including any opinions offered by Plaintiffs' experts at their depositions or at trial.

Samsun Lampotang, Ph.D.

5. J. PD

Dated: June 2, 2017

Roder G, et al. Intra-operative rewarming with Hot Dog resistive heating and forced-air heating: a trial of lower-body warming. *Anaesthesia* 2011;66:667-74.

- ". Avidan MS, et al. Convection warmers not just hot air. *Anaesthesia* 1997;52: 1073-1076.
- Bernards AT, et al. Persistent Acinetobacter baumannii? Look inside your medical equipment. *Infection Control & Hospital Epidemiology* 25.11 (2004): 1002-1004.
- McGovern PD, et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone Joint Surg Br.* 2011; 93-B:1537-44.
- <sup>v</sup> Huang JK, et al. The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk? *Critical Care*. 2003;7:R13-6.
- <sup>vi</sup> Moretti B, et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? *J. Hosp. Infect.* 2009;73:58-63.
- <sup>vii</sup> Birgand G, et al. Air contamination for predicting wound contamination in clean surgery: A large multicenter study. *American Journal of Infection Control* 43.5 (2015): 516-521.
- Loftus RW, et al. Hand contamination of anesthesia providers is an important risk factor for intraoperative bacterial transmission. *Anesthesia & Analgesia* 112.1 (2011): 98-105.
- <sup>ix</sup> Munoz-Price LS, et al. Interactions between anesthesiologists and the environment while providing anesthesia care in the operating room. *American Journal of Infection Control* 41.10 (2013): 922-924.
- \* Lampotang S, et al. The effect of a bellows leak in an Ohmeda 7810 ventilator on room contamination, inspired oxygen, airway pressure, and tidal volume. *Anesthesia & Analgesia* 101.1 (2005): 151-154.

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- <sup>\*ii</sup> Memarzadeh, F. Active warming systems to maintain perioperative normothermia in hip replacement surgery. Letters to the Editor Journal of Hospital Infection. 2010:75; 325-337.
- Berríos-Torres SI, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. *JAMA surgery* (2017).
- xiv Wagner K, et al. Comparison of two convective warming systems during major abdominal and orthopedic surgery. *Canadian Journal of Anesthesia* 55.6 (2008): 358-363.

<sup>&</sup>lt;sup>\*v</sup> Albrecht M, et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *American Journal of Infection Control* 39.4 (2011): 321-328.

xvi Moon T, et al. Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient. Open Access J Surg. 2017; 4(1): 555627. DOI: 10.19080/OAJS.2017.04.555627.

#### **CURRICULUM VITAE**

Samsun Lampotang, Ph.D.

#### PRESENT APPOINTMENT

Professor, Department of Anesthesiology, University of Florida (UF) College of Medicine, Gainesville, Florida, 2005 - present

Innovations Director, UF Health Shands Experiential Learning Center, July 2015- present Director, UF Clinical & Translational Science Institute (CTSI) Simulation Core Service, April 2014 - present

Director, Center for Safety, Simulation & Advanced Learning Technologies, University of Florida College of Medicine, Gainesville, Florida, 2009 - present

Affiliate Professor, Department of Biomedical Engineering, College of Engineering, University of Florida, Gainesville, Florida, 2011 - present

Affiliate Professor, Department of Mechanical & Aerospace Engineering, College of Engineering, University of Florida, Gainesville, Florida, 2005 - present

Affiliate Professor, Department of Electrical and Computer Engineering, College of Engineering, University of Florida, Gainesville, Florida, 2005 – present

Graduate Faculty Status, University of Florida College of Engineering, Gainesville, Florida, 1996 - present

Member, Brain Institute, University of Florida, Gainesville, Florida, 1996 - present

## **EDUCATION**

B.S. (Honors), Mechanical Engineering, Brunel University, England, July 1981 M.S., Mechanical Engineering, University of Florida, August 1984 Ph.D., Mechanical Engineering, University of Florida, August 1992

#### PREVIOUS APPOINTMENTS

Engineering Apprentice, Forges Tardieu Ltd, Port Louis, Mauritius, March-August 1977 Trainee Project Engineer, British Oxygen Medical Gases Ltd, Brentford, Middlesex, England, April-September 1978

Precision Machinist/Fitter, Acmade International Ltd, Denham, Middlesex, England, April-September 1979

Design Draughtsman, Tate & Lyle Agribusiness Ltd, Bromley, England and Glasgow, Scotland, April-September 1980

Graduate Teaching Assistant, Mechanical Engineering Department, University of Florida, January-June 1982

Extern Project Engineer, Ohmeda Anesthesia Systems, Madison, Wisconsin, May-July, 1987 (Co-designed and built first working prototype of Gainesville Anesthesia Simulator (GAS) which would become the Human Patient Simulator (HPS)

- Graduate Research Assistant, Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida, August 1982- May 1992 (Master's Candidate in Mechanical Engineering ('82-'84); Doctoral Candidate in Mechanical Engineering ('84-'92); worked exclusively on design and development of Gainesville Anesthesia Simulator/Human Patient Simulator from '87-'90)
- Post-Doctoral Associate, Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida, May 1992-August 1992
- Visiting Assistant Professor, Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida, August 1992-October 1993
- Visiting Affiliate Assistant Professor, Department of Mechanical Engineering, College of Engineering, University of Florida, Gainesville, Florida, October 1992-October 1993
- Assistant Professor, Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida, October 1993-1999
- Affiliate Assistant Professor, Department of Mechanical Engineering, College of Engineering, University of Florida, Gainesville, Florida, October 1993-1999
- Affiliate Assistant Professor, Department of Electrical and Computer Engineering, College of Engineering, University of Florida, Gainesville, Florida, June 1, 1996-1999
- Associate Professor, Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida, 1999-2005
- Affiliate Associate Professor, Department of Mechanical Engineering, College of Engineering, University of Florida, Gainesville, Florida, 1999-2005
- Affiliate Associate Professor, Department of Electrical and Computer Engineering, College of Engineering, University of Florida, Gainesville, Florida, 1999-2005

#### HONORS AND AWARDS

American Society of Anesthesiologists

First Prize for Scientific & Educational Exhibit, (Gainesville Anesthesia Simulator/Human Patient Simulator), 1987

First Prize for Scientific & Educational Exhibit, (Training Devices), 1992

Exceptional Merit Award for Scientific & Educational Exhibit, (Neuromuscular Blockade Training Device), 1994

First Prize for Scientific & Educational Exhibit (Virtual Anesthesia Machine), 2001

Third Prize for Scientific & Educational Exhibit, (Augmented Anesthesia Machine), 2008

Exceptional Merit Award for Scientific & Educational Exhibit (Pulse oximetry – An accurate monitor for detection of hypoventilation, 2009

First Prize for Scientific & Educational Exhibit, (Mixed simulator of central venous access), 2011

Second Place Award for Scientific & Educational Exhibit, Mixed simulator of thoracic regional anesthesia), 2013

#### Anesthesia Patient Safety Foundation

Ellison C. Pierce Award for Best Scientific Exhibit on Patient Safety, (Imaging stylet), 1997 Ellison C. Pierce Award for Best Scientific Exhibit on Patient Safety, (Virtual Anesthesia Machine), 2001

Ellison C. Pierce Award for Best Scientific Exhibit on Patient Safety, (Mixed simulator of thoracic regional anesthesia), 2013

International Anesthesia Research Society Second Place for Scientific & Educational Exhibit, (Imaging stylet), 1998

IEEE Virtual Reality Meeting Nominated for Best Short Paper, 2013

International Business Machines (IBM)
IBM Faculty Development Award, 2005

InterService/Industry Training, Simulation and Education Conference
Best Paper Award, Emerging Concepts and Innovative Technologies Section, 2012

Marquis's Who's Who in the South and Southwest, 1998

New York State Society of Anesthesiologists

Postgraduate Assembly of Anesthesiology, Honorable Mention for Scientific Exhibit, (Imaging stylet), 1998

Partnership in Global Learning, 3rd Annual Meeting, Sao Paulo, Brazil

Best paper in the category "e-learning Collaborative Environment: Practical Experiences and Theoretical Fundamentals", 2005

Scholarship from Government of Mauritius, 1977 - 1981

Society for Education in Anesthesia

SEA/Duke Award for Excellence and Innovation in Anesthesia Education,

Nominated 2003, 2004

Awarded SEA/Duke Award for Excellence and Innovation in Anesthesia Education, 2007 (only non-physician to have received this award to date)

Society for Simulation in Healthcare

Best abstract for Technology Innovation, 2013 International Meeting on Simulation in Healthcare meeting (An iPad simulation of skin prepping), Orlando, FL

Society for Technology in Anesthesia

Outstanding abstract for technology innovation, (Imaging stylet), January 1998

Best ASA abstract for the application of technology innovation, (Imaging stylet), October 1998

Best Abstract for the Application of Technology to Education, (Virtual Anesthesia Machine), January 2000

University of Florida

UF Presidential Recognition Award, March 27, 1989.

Award for Innovative Excellence in Teaching, Learning and Technology, 2003

Nominated for the Ernest L. Boyer International Award for Excellence in Teaching, Learning and Technology, 2003

Nominated for the Society of Teaching Scholars, October 2003

Technology Innovator, University of Florida Office of Technology and Licensing, March 2011

Technology Innovator, University of Florida Office of Technology and Licensing, March 2012

Technology Innovator, University of Florida Office of Technology and Licensing, March 2013

Faculty Enhancement Opportunity award, \$23,593, received April 10, 2013

Nominated for University of Florida Research Foundation Professorship award by Timothy E. Morey, MD, Anesthesiology chair on February 11, 2015

University of Florida College of Medicine Exemplary Teacher award for AY 14-15

**LICENSURE:** Florida Engineer-in-Training (EIT), 1986

#### **SOCIETY MEMBERSHIPS**

American Society of Anesthesiologists, 1992 - present American Society of Mechanical Engineers, 1992 – 1999 American Society for Testing and Materials, 1993 – 1999 Anesthesia Patient Safety Foundation, 1991 - present Florida Society of Anesthesiologists, 1992 - present Society for Education in Anesthesia, 2001 - present Society for Technology in Anesthesia, 1993 – present Society for Simulation in Healthcare, 2003 - present

#### **EDITORIAL BOARDS**

#### **Current Editorial Board Commitments**

Association for Computing Machinery (ACM) Computing Surveys, Reviewer 2014 – present To review ACM CSUR-2014-0427

Anesthesia and Analgesia, Reviewer, 2001 – present

Reviewed manuscript 07-1736, Version 1, January 8, 2008

Reviewed manuscript 07-1330, Version 2, February 22, 2008

Reviewed manuscript 07-1330, Version 3, May 13, 2008

Reviewed manuscript 08-00960, Version 1, July 9, 2008

Reviewed manuscript 08-01166R1, Version 1, August 25, 2008

Reviewed manuscript AA-D-11-00814, Version 1, June 1, 2011

Reviewed manuscript AA-D-14-01599, Version 1, December 4, 2014

BioMed Central, Reviewer, 2014 - present

Reviewed manuscript from Japan about debriefing methods in simulation-based sedation training courses, August 25, 2014

BMJ Quality & Safety, Reviewer, 2013 – present Reviewed manuscript bmjqs-2012-001797.R1, April 4, 2013 Clinical Window Scientific Journal, Editorial Board Member, 2010 – present

IEEE Transactions of Biomedical Engineering, Reviewer, 2003 - present Reviewed manuscript TBME-00291-2003, October 28, 2003 Reviewed manuscript TBME-01351-2011, December 12, 2011

IEEE Virtual Reality, Reviewer, 2014 - present Reviewed manuscript #142, October 16, 2014

Simulation in Healthcare, Editorial Board Member, 2005 – present

Reviewed SIH-D-08-00005, March 18, 2008

Reviewed SIH-D-08-0005R1, May 28, 2008

Reviewed SIH-D-08-00043, June 27, 2008

Reviewed SIH-D-08-00005R2, July 24, 2008

Reviewed SIH-D-09-00013, April 21, 2009

Reviewed SIH-D-09-00060, August 27, 2009

Reviewed SIH-D-09-00086, November 2, 2009

Reviewed SIH-D-09-00093, November 20, 2009

Reviewed SIH-D-10-00024, April 7, 2010

Reviewed SIH-D-10-00022, April 7, 2010

Reviewed SIH-D-10-00112, September 28, 2010

Reviewed SIH-D-10-00142, November 22, 2010

Reviewed SIH-D-10-00151R1, January 28, 2011

Reviewed SIH-D-10-00142R1, February 4, 2011

Reviewed SIH-D-10-00151R3, May 4, 2011

Reviewed SIH-D-11-00120, October 19, 2011

Reviewed SIH-D-11-00154, December 27, 2011

Reviewed SIH-D-12-00021, March19, 2012

Reviewed SIH-D-12-00097, June 27, 2012

Reviewed SIH-D-12-00090, June 28, 2012

Reviewed SIH-D-12-00166, September 26, 2012

Reviewed SIH-D-12-00222, January 9, 2013

Reviewed SIH-D-13-00062, May 6, 2013

Reviewed SIH-D-14-00091, July 7, 2014

Reviewed SIH-D-14-00091-R1, December 5, 2014

# **Completed Editorial Board Commitments**

Anesthesiology, Reviewer, 1999 – 2003

Reviewed manuscript 200307003, Version 1, July 25, 2003

Reviewed manuscript 200307004, Version 1, August 7, 2003

Anesthesia and Analgesia, Reviewer, 2001 – present Reviewed manuscript 03-0007, Version 1, February 5, 2003 Reviewed manuscript 04-0065, Version 1, March 5, 2004 Reviewed manuscript 03-1334, Version 2, May 20, 2004 Reviewed manuscript 05-0250, Version 1, March 5, 2005 Reviewed manuscript 06-0533, Version 1, May 26, 2006 Reviewed manuscript 07-0075, Version 1, February 8, 2007 Reviewed manuscript 07-0527, Version 1, April 11, 2007 Reviewed manuscript 07-1330, Version 1, October 8, 2007

Internet Journal of Anesthesiology, Editorial Board, 2000

Journal of Clinical Anesthesia, Guest Technical Reviewer, 1993

# Journal of Clinical Monitoring

Guest Technical Reviewer, 1987-1994

Editorial Board Member, 1995-1997

Reviewed manuscript B766, Version 1, August 22, 1994

Reviewed manuscript B771, Version 1, November 8, 1994

Reviewed manuscript B766, Version 1, August 22, 1994

Reviewed manuscript B781, Version 1, January 16, 1995

Reviewed manuscript B786, Version 1, February 12, 1995

Reviewed letter to editor, Version 1, February 26, 1995

Reviewed manuscript B806, Version 1, March 10, 1995

Reviewed manuscript B824, Version 1, July 20, 1995

Reviewed manuscript B786, Version 1, February 12, 1995

Reviewed manuscript B853, Version 1, January 21, 1996

Reviewed manuscript B875, Version 1, February 7, 1996

Reviewed manuscript OA896, Version 1, August 30, 1996

Reviewed manuscript JOCM1035, Version 1, January 2, 1997

Reviewed manuscript JOCM1037 Version 1, January 12, 1997

Reviewed manuscript JOCM1091, Version 1, December 15, 1997

# Journal of Clinical Monitoring and Computing

Editorial Board Member, 1998 – 2000

Reviewed manuscript JOCM1209, Version 1, May 14, 1999

Reviewed manuscript JOCM1268 Version 1, February 28, 2000

## Simulation in Healthcare, Editorial Board Member, 2005 - present

Reviewed SIH D-05-00009, October 30, 2005

Reviewed SIH D-06-00030[1], September 19, 2006

Reviewed SIH-D-06-00058, February 21, 2007

Reviewed SIH-D-06-00030[2], April 10, 2007

Reviewed SIH-D-07-00026, May 11, 2007

#### VISITING PROFESSORSHIPS

Hokkaido University School of Medicine, Sapporo, Japan, April 24, 1995

Sapporo Medical College, Sapporo, Japan, April 24, 1995

University of North Carolina, Chapel Hill, Department of Anesthesiology, August 5-6, 1998

University of Toronto, Toronto General Hospital, Toronto, Ontario, Canada, September 25, 1998

Hong Kong University, Department of Anesthesiology, Queen Mary Hospital, October 31, 1998

State University of New York, Department of Anesthesiology, Stony Brook, New York, December 2, 1999

St. Michaels Hospital, University of Toronto, Toronto, Canada, August 23, 2000

Nanjing Medical University, Department of Anesthesiology, Nanjing, China, September 12, 2002

Jiangsu Province Hospital, Nanjing, China, September 13, 2002

University of California Davis Medical Center, Department of Anesthesiology, Sacramento, California, December 9-11, 2002.

Universidad Veracruzana, Hospital Escuela de Ginecologia y Obstetricia, Veracruz, Mexico, July 17 – 18, 2003

University of Miami, Department of Anesthesiology, Miami, Florida, November 19, 2003

Beijing Institute of Heart, Lung and Blood Vessel Diseases, An Zhen Hospital of Capital University of Medical Science, Beijing, China, "Virtual Anesthesia Machine", September 16, 2004

Beijing Union Medical College Hospital, Department of Anesthesiology, Beijing, China, "Instructor version of Virtual Anesthesia Machine simulation", September 16, 2004

Northwestern University, Feinberg School of Medicine, Chicago, IL, "Anesthesia machine function". November 5 – 6, 2005

Hôpitaux Universitaires de Genève, Département d'anesthésiologie, Geneva, Switzerland, "Sécurité des appareils d'anesthésie: vérification avant utilisation et sa simulation ", June 19, 2006 (delivered in French)

Northwestern University, Northwestern Memorial Hospital, Chicago, Illinois, September 7-8, 2007

Hospital for Special Surgery, New York, New York, April 16-17, 2008

Brigham and Women's Hospital, Boston, Massachusetts, June 3-4, 2008

Northwestern University, Northwestern Memorial Hospital, Chicago, Illinois, September 12, 2009

University of Toronto Wilson Centre/Toronto General Hospital, September 30, 2010

Northwestern University, Northwestern Memorial Hospital, Chicago, Illinois, February 4, 2012

Stanford University, Palo Alto, CA, January 30, 2014

Northwestern University, Chicago, Illinois, February 14, 2014

#### TEACHING AND ADVISING

State of Florida

Department of Education

Curriculum Development Team Member for "Health Sciences Patient Simulator Curriculum Scenarios," 1994

University of Florida College of Business Administration

Faculty Supervisor for Graduate Students

Robert M. Carr, Business Administration, 10/05–08/06

Neal Johnson, Business Administration, 4/4/95-4/30/96

Edward SaGomes, Business Administration, 1/4/94-5/12/95

## University of Florida College of Engineering

Faculty Supervisor for Post-Doctoral Students

Hwang, Yongho, Computer and Information Science and Engineering, 10/08 - 5/10

#### Faculty Supervisor for Graduate Students

Ikram Ali, Electrical Engineering, 3/8/93-8/11/94

Thandu K. Balasubramanian, Electrical Engineering

Member, Master's Thesis Committee, 1996-1997

Yash Bisht, Computer and Information Science and Engineering, 12/20/11 – present

Tariq Bucch, Electrical Engineering, 8/23/93-8/11/94

Lucas Cascardo, Mechanical Engineering, 9/10/93-9/3/94

Priscilla Chen, Electrical Engineering, 6/10/96-8/97

Chairman, Master's Thesis Committee, 1996-1997

Joon Hao Chuah, Computer and Information Science and Engineering,

Member, Doctoral supervisory committee, November 2012 – August 2013

Andrew Cordar, Computer and Information Science and Engineering,

Doctoral candidate, January 2014 – present, funded by NSF/HCC grant

Ed Cometz, Computer Information Sciences, 1/5/93-4/30/93

Tom Cowan, Biomedical Engineering Master's project, 2012

Goeto Dantes, Biomedical Engineering undergraduate student, 2013 – 2015; admitted to UF medical school

Ashish Desai, Electrical Engineering, 10/5/92-11/13/92

Zach Ezzell, Computer and Information Science and Engineering,

Member, Doctoral supervisory committee, September 2010 – December 2012

Diego de la Hoz, Undergraduate UF Mechanical Engineering student; anti-DVT pressure sock monitoring

Sanghyun Jeon, Computer and Information Science and Engineering,

Member, Doctoral Dissertation Committee, 5/05 - 12/10

Supervisor, E-learning system deployment, Summer C, 2005

Marnix van Kempen, Electrical Engineering, 10/94-9/95

Member, Master's Thesis Committee, 1994-1995

Hamid Khan, Electrical Engineering, 1/5/93-8/6/93

Aaron Kotranza, Computer and Information Science and Engineering,

External Member, Doctoral Dissertation Committee, Graduated December 2009

Gilliean Lee, Computer and Information Science and Engineering,

Substitute Member, Doctoral Dissertation Committee, 7/12/05

David Lizdas, Computer Science, 5/02 - 5/03

Sungwook Moon, Computer and Information Science and Engineering,

Supervisor, Implementation of database and analysis tools for anesthesia machine pre-

use check survey, 3/17/05 - 5/2/05

External committee member, Doctoral supervisory committee, Aug 2006 – Dec 2011

Jason Nadrowski, Electrical Engineering, 6/13/95-8/97

Co-chairman, Master's Thesis Committee, 1995-1997

Matthew Peterson, Biomedical Engineering, BME 6010, Clinical Preceptorship, Summer C, 2005

John Quarles, Computer and Information Science and Engineering,

Member, Doctoral supervisory committee, September 2005 – 2010

Ashvin Ramachandran, Biomedical Engineering Department, Master's project, comparing two identifiers using a SmartPhone, to save time and prevent inaccuracy when doing so manually, 8/2013-2014

Aneel Rijhwani, Electrical Engineering, 1/9/95-5/31/96

Member, Master's Thesis Committee, 1995-1996

Andrew Robb, Computer and Information Science and Engineering,

Member, Doctoral supervisory committee, January 2011 - present; funded by NSF/HCC grant

Anwer Sultan, Electrical Engineering, 8/93-8/95

William J. Thoman, Engineering Sciences, 6/10/96-5/98

Co-chairman, Master's Thesis Committee, 1996-5/98

Qiaogan Wang, Electrical Engineering, 8/93-12/93

#### Faculty Advisor for Undergraduate Students

Chris Auzins, Electrical Engineering, 6/93-5/96

Ryan Chin, Engineering Sciences, 6/96-5/97

Jim Clift, Engineering Sciences, 8/94-12/94

Jovanni Conway, Engineering Sciences, 5/97 - present

Supervisor for individual study EGM 4905, Fall semester, 1997

Supervisor for individual study EGM 4905, Spring semester, 1998

Walter Dobbins, Electrical Engineering, 11/98 – 6/00

Scott Gilloon, Electrical Engineering, 5/97-8/97

Todd Gjervold, Mechanical Engineering

Adviser for Honors project, 10/98 - 4/99

David Lizdas, July 2000 – December 2000

Justin Cort Sanchez, Engineering Sciences, 5/98 – present

Highest Honors Committee, July 27, 2000

Michael Wenning, Electrical and Computer Engineering

Supervisor for Senior Design Project, EEL 4914, Spring semester 1998

# Faculty Advisor for High School Students

Shalin Soni, UF Student Science and Training Program (SSTP), 6/15/03 – 8/2/03

#### Lectures for Engineering Courses

Guest Lecturer: EGM 3900--Introduction to Biomedical Engineering Design, February 17,

1994

Guest Lecturer: EEL 5934--Medical Instrumentation, March 24, 1994

Guest Lecturer: EGM 3900--Introduction to Biomedical Engineering Design, February 7,

1995

Guest Lecturer: EGM 3900--Introduction to Biomedical Engineering Design, March 19,

Guest Lecturer: EEL 4930--Biomedical Signals: Measurement and Processing, April 2,

1997

Guest Lecturer: EGM 3900--Introduction to Biomedical Engineering Design, September 9,

1997

Guest Lecturer: EGM 4901--BioFluids, November 24, 1997

Guest Lecturer: EGM 3900--Introduction to Biomedical Engineering Design, November

25, 1997

Guest Lecturer: Biomedical Engineering Seminar: Plastic Optical Fiber Imaging Stylet, April 21, 1998

Guest Lecturer: EGM 6934--Biomedical Engineering and Physiology: How the Intellectual

Property of the Human Patient Simulator is Protected, December 9, 1998

Guest Lecturer: EMA 6938—Biomedical Engineering Seminar: A cervical motion sensor for the human patient simulator, September 14, 1999

Guest Lecturer: EGM 6934—Biomedical Engineering and Physiology: Intellectual Property of the Human Patient Simulator, December 8, 1999

Guest Lecturer: BME 6936—Biomedical Engineering Seminar: The Virtual Anesthesia Machine - Interactive Simulation on the Web, December 3, 2003

Guest Lecturer: Demo of simulators to College of Education class EDG 6931: Games and Simulations for Teaching and Learning taught by Al Ritzhaupt; October 27, 2011

Guest Lecturer: Demo of simulators and doctoral research opportunities to BioMedical Engineering Department PhD applicants at the request of Dr. van Oostrom, February 17, 2012

Project Supervisor for Senior Design Courses, EML4501

Scott Brient, Fall 1993

Mark Nelson, Fall 1993

Supervisor for Individual Study, EEL 4905

Colin Cheung-Seekit, Spring 1997

University of Florida College of Liberal Arts & Sciences

AJ Tucker, undergraduate student volunteer – Senior student pursuing a degree in Biology in CLAS; March – August 2014

University of Florida College of Medicine

Department of Anesthesiology

Anesthesia Course for Engineers and Marketing Personnel (ACEM)

Simulator Session, May 5, 1994

Simulator Session, September 22, 1994

Simulator Session, February 9, 1995

Simulator Session, December 1, 1995

Simulator Session, February 8, 1996

Simulator Session, March 28, 1996 Simulator Session, September 19, 1996 Simulator Session, February 27, 1997 Simulator Session, May 8, 1997 Simulator Session, October 8, 1997 Simulator Session, February 12, 1998 Simulator Session, October 8, 1998 Simulator Session, April 27, 2000 Simulator Session, November 2, 2000 Simulator Session, March 29, 2001 Simulator Session, November 1, 2001 Simulator Session, May 2, 2002 Simulator Session, October 31, 2002 Simulator Session, March 27, 2003 Simulator Session, October 30, 2003 Simulator Session, March 25, 2004 Simulator Session, November 4, 2004 Simulator Session, March 24, 2005 Simulator Session, November 3, 2005 Simulator Session, March 23, 2006 Simulator Session, November 2, 2006 Simulator Session, March 8, 2007 Simulator Session, September 20, 2007 Simulator Session, November 8, 2007 Simulator Session, April 24, 2008 Simulator Session, July 18, 2008 Simulator Session, September 18, 2008 Simulator Session, March 26, 2009 Simulator Session, September 17, 2009 Simulator Session, February 9, 2010 Simulator Session, March 25, 2010 Simulator Session, April 15, 2010 Simulator Session, May 20, 2010 Simulator Session, September 16, 2010 Simulator Session, April 28, 2011 Simulator Session, May 19, 2011 Simulator Session, September 22, 2011 Simulator Session, October 6, 2011 Simulator Session, January 26, 2012 Simulator Session, February 23, 2012 Simulator Session, April 19, 2012 Simulator Session, May 24, 2012 Simulator Session, September 20, 2012 Simulator Session, October 4, 2012 Simulator Session, March 20, 2013 Simulator Session, April 18, 2013

Simulator Session, May 23, 2013

Simulator session, November 13, 2013 to Covidien leadership management team

Simulator Session, December 5, 2013

Simulator Session, March 13, 2014

Simulator Session, May1, 2014

Simulator Session, September 25, 2014

# Faculty Advisor for Anesthesiology Residents

Dietrich Gravenstein, MD; imaging intubating stylet, non-invasive hemoglobin Monitor, 1992

Bai Xi Chen, MD; effect of an anesthesia ventilator bellows tear; resulted in A&A peer-reviewed paper, 1997

John Hall, MD; extracting respiratory rate from pulse oximeter plethysmogram, 1997

Edwin Liem, MD, 1999 – 2001; Virtual Anesthesia Machine simulation and web site; Faculty Advisor for Anesthesiology Resident research, September 2000 - February, 2001

Gautam Sehgal, MD, UF Anesthesiology Department 2006 – 2007

Sinan Yavas, MD; simulation of pharmacokinetics/dynamcis of propofol and fospropofol, 2007-2008

Gregory Goldenhersh, MD; pulse oximeter motion artifact as cosnciousness monitor, 2013

Amelia Fiastro, MD; automated verbal prompt from an infusion prompt instructing patients to self-clear a kink in the IV line before an audible alarm occurs, 2013-14

Shazia Mohammad, MD; effect of fresh gas flow on delivered tidal volume during pressure controlled ventilation, 2014 – present

Heather Reed, MD; simulation-based study on how rudeness affects clinical performance, 2014 – present

Catherine (Kitty) Jane Coleman, MD, preparation of manuscript for submission to Simulation in Healthcare about a thoracic regional anesthesia simulator helping to develop a modified RA technique, 2015 – present

Joseph LaGrew, MD, CA-1; clinical evaluation of a talking pulse oximeter; 12/2015 – present

# Research Advisor for Medical Students

Eric Barroso, 2003

Isaac Luria, 2013, Summer Research Project – Urine Drainage Study

# Mentoring Fellows, Junior, Mid-Level and Senior Faculty

Gang Zheng, MD, UF Anesthesiology Department 2008 - present

Harshdeep Wilkhu, MD, UF Anesthesiology Department 2007 - 2008

Victor Zhang, MD UF Anesthesiology Department 2004 – 2006

Steven Robicsek, MD, PhD, UF Anesthesiology Department 2004 – 2006; application to FEO program, 2014

Edwin B. Liem, MD, University of Louisville, Anesthesiology Department 2001 – 04 John Werning, MD, UF Surgery Department, 2007-2008; applied for a National Patient

- Safety Foundation grant to reduce incidence of wrong-sided surgery
- Albert R. Robinson, MD, UF Anesthesiology Department 2007-present
- Yong G. Peng, MD, PhD, UF Anesthesiology Department 2007-2008
- Andrew Pitkin, MD, UF Anesthesiology Department 2008 present; mentored on writing a full IHAF grant on which he was PI with Lampotang as Co-Investigator
- Alex Matveevskii, MD, UF Anesthesiology Department 2008
- Barys Ihnatsenka, MD, UF Anesthesiology Department 2010 present; mentored on writing a full IHAF grant on which he is PI with Lampotang as co-Investigator; internal grant led to extramural American Society for Regional Anesthesia grant
- Patrick Tighe, MD, UF Anesthesiology Department 2010 present (Redirected offer of keynote speaking engagement on robotic anesthesia at STA 2012 meeting to Dr. Tighe)
- Gail Randel, MD, Faculty at Northwestern University 2011- present (manuscript help on 7/22/2011 on Development of an Airway Management Assessment Tool by Using Bloom's Taxonomy; submitted to JCA JCA-S-11-00154)
- Huong Thi (Cindy) Le, MD, UF Anesthesiology Department 2011 present Lou Moy, MD, UF Urology Dept., 2011- present, co-investigator on multiple proposals related to urine dependent loops
- Linda Le-Wendling, MD, UF Anesthesiology Department October 2011 to present (Venous Air Embolism, Clinical Quality Award grant; Thoracic regional anesthesia simulator IRB-02 applications, learngin and patient outcome studies, writing the simulation "first" paper)
- William B (Brit) Smith, MD, UF Anesthesiology Department April 2012 present (Grant proposal to IHAF; Urine dependent loop study; CVA simulator learning outcome study)
- Adam Wendling, MD; UF Anesthesiology Department, co-investigator on NSF/HCC grant since July 2012; FEO application 2014
- Avner Sidi, MD, UF Anesthesiology Department, collaboration on portability of scenarios developed in Israel to American residency programs, 2012 present
- Joshua Sappenfield, MD, Junior Faculty, UF Dept. of Anesthesiology, August 13, 2013 present
- Peggy White, MD, Junior UF Anesthesiology faculty, March 2014; mentored on writing a full IHAF grant on which she is PI with Lampotang and Brenda Fahy, MD as Co-Investigators
- David Edwards, MD, Junior Faculty, Massachusetts General Hospital, Anesthesiology Department, April 2014 present; co-investigator on ASRA grant
- Chris Giordano, MD; UF Anesthesiology Dept; on simulation-based study on how rudeness affects clinical performance, 2014
- Rene Przkora, MD, UF Anesthesiology Dept; on letter of intent to APSF for a simulation-based study using Virtual Humans to train anesthesiologists in the affective skills required for managing difficult patients, February 2015 –
- Melissa Vu, MD, UF Anesthesiology Department; assigned her PI role on a small (<\$20K grant on which I was PI); 10/22/15 present
- Sang-Chun Choi, MD, MS, an emergency room physician from Ajou University, South Korea started a one-year simulation fellowship at CSSALT

Mentoring Anesthesiology Residents

Nicole Dubija, UF Anesthesiology Department 2004 – present Gregory Goldenhersh, MD, UF Anesthesiology Department 2012 - present Gautam Sehgal, MD, UF Anesthesiology Department 2006 – 2007 Sinan Yavas, MD, UF Anesthesiology Department 2007-2008

Mentoring Nurses

Michele Brunges, RN, UF Health – informed her of FHSA RFP and helped write proposal

Chrsistine Foley-Brinza, RN, UF Health – informed her of FHSA RFP and helped write proposal

Terry Sullivan, RN, UF Health, mentored her on BC/BS Florida Blue Foundation and submitting a poster to UF College of Medicine Celebration of Research and

## Mentoring Anesthesia Techs

Tony Olcheske, Anesthesia Tech interested in research and 3D printing, 2014

# Morning Conferences

Anesthesia machine pre-use check, 7/21/99

Ventilators and breathing circuits, 7/26/99

Anesthesia machine pre-use check, 7/12/00

Anesthesia machines and breathing circuits, August 1, 2000

Mechanics I: the anesthesia machine, July 23, 2001

Virtual Anesthesia Machine, March 20 and 21, 2002

The anesthesia machine, 7/22/02

Mechanics: The anesthesia machine, the anesthesia machine check, July 14, 2003

The APSF anesthesia machine workbook: high pressure system. August 19, 2003

The anesthesia machine, July 7, 2004

The anesthesia machine, July 6, 2005

The anesthesia machine, July 5, 2006

The anesthesia machine pre-use check, Jan 30, 2007

Troubleshooting the anesthesia machine, February 12, 2007

The anesthesia machine, August 16, 2007

The Virtual Anesthesia Machine, July 6, 2010

The anesthesia machine, July 27, 2010

The Virtual Anesthesia Machine, August 23, 2010

Simulation in Anesthesia, September 20, 2010

CA1-Small Groups, Troubleshooting the anesthesia machine, 2/14/2012

Interns lecture, The anesthesia machine pre-use check, part 1, May 2, 2012

Interns lecture, The anesthesia machine pre-use check, part 2, May 9, 2012

The Virtual Anesthesia Machine, Morning lecture, November 15, 2012

The Virtual Anesthesia Machine, Morning lecture, July 22, 2013

Failure Modes of Anesthesia Machines, Morning Lecture, August 26, 2013

Anesthesia Machine Pre-Use Check, Morning lecture, July 15, 2014

Normal Operation of Anesthesia Machines, July 16, 2014

Managing Failure Modes of Anesthesia Machines, July 17, 2014

Preventing and Managing Surgical Fires, August 27, 2014

Applied Pharmacokinetics and Pharmacodynamics in Anesthesia: *Delivered PK/PD lecture as a morning lecture for the first time; this brand lecture was created in response to a manuscript I reviewed that bemoaned that anesthesia residents are not taught PK/PD as it applies to anesthesia.* December 9, 2015

# Hands-on Learning Sessions

Pre-use Machine Check for Anesthesiology Interns

July 28, 2011, 2 hours

June 4, 2012, 7 interns taught, 3 separate sessions

June 5, 2012, 8 interns taught, 4 separate sessions

November 5, 2014, VAM and anesthesia machine pre-use check for interns, 2 hours

November 6, 2014, VAM and anesthesia machine pre-use check for interns, 2 hours

# Pre-use Machine Check for Anesthesiology Residents

July 1993, 5 days

July 1994, 5 days

July 1995, 4 days

July 1996, 4 days

July 1997, 3 days

July 1998, 3 days

July 1999, 3 days

July 2000, 3 days

July 2001, 2 days

July 2002, 2 days

July 2002, 2 days

July 2003, 2 days July 2004, 2 days

July 2005, 2 days

July 2006, 2 days

July 2008, 2 days

July 28, 29, 2010, 2 days

July 19, 20, 2012, Hands-on anesthesia machine pre-use check instruction – 6 sessions of 45 minutes each to 6 groups of 2 residents each per day for 2 consecutive days

July 22, 2013: Anesthesia Machine Pre-Use Check Hands-on Sessions: 18 residents taught, 6 separate sessions

July 15, 2014, Hands-on performance of Anesthesia Machine Pre-use Check on an intact anesthesia machine: 11 sessions of 30 minutes each with 11 groups consisting of 22 residents (2 residents in each group)

July 16, 2014, Hands-on performance of Anesthesia Machine Pre-use Check on an anesthesia machine planted with faults: 11 sessions of 30 minutes each with 11 groups consisting of 22 residents (2 residents in each group)

July 31, 2015, Hands-on performance of Pre-use check on an anesthesia machine with

planted faults: 11 sessions of 30 minutes each with 11 groups consisting of 22 residents (2 residents in each group)

ITE training sessions for residents (led by Mark Rice, MD)

Helped teach anesthesia machine segment – September 22, 2011

Pre-use Machine Check for Shands Hospital Block Room Nurses

November 22, 1999

Evening anesthesia machine training session for In Training Exam (ITE); 2 hours, September 12, 2013

Teaching graduating residents

Hands-on tutorial on piston ventilator anesthesia machines (Drager Apollo and Fabius GS) to Everett Petersen, Brad Brian, Adam Fier and Michael Cometa on May 23, 2011 Hands-on training of graduating residents (Steve Yannaras, Justin Cueto) on Drager ventilators (1 hour hands-on) June 26, 2012

Simulator Problem-Based Learning Session

Neuroanesthesia, December 8 and 9, 1997

Intracranial pressure, December 18 and 19, 1997

Simulator-Based Basic Skills Training Course

Rumi Watanabe, MD (Visiting resident from Dokkyo University, Japan)

The Virtual Anesthesia Machine for new residents, July 23, 2001 (3 hrs)

The Virtual Anesthesia Machine for new residents, July 22, 2002 (3 hrs)

The Virtual Anesthesia Machine for new residents, July 10, 2003 (3 hrs)

The Virtual Anesthesia Machine for new residents, July 6, 2004 (3 hrs)

The Virtual Anesthesia Machine for new residents, July 6, 2005 (3 hrs)

The Virtual Anesthesia Machine for new residents, July 11, 2006 (3 hrs)

The Virtual Anesthesia Machine for new residents, July 11, 2008 (3 hrs)

# Department of Physiology

Respiratory physiology instruction for first-year medical students using the Human Patient Simulator (5 days, annually), 1993 - 2000

# University of Florida College of Dentistry

Simulation education at the UF Health Science Center and avenues for collaboration, January 28, 2008

# University of Florida College of Nursing

Presentation of the VAM website, February 8, 2008

# University of Florida Office of Academic Technology

Presentation on transparent reality simulation and e-learning for the Faculty Showcase, November 15, 2004

# University of Florida Simulation Faculty Learning Community Screen-based, web-enabled and panoramic simulations, April 28, 2008

University of Technology, Eindhoven, The Netherlands Faculty Supervisor for Engineering Graduate Students

Marnix van Kempen, 1994-1995

University of Utah, Department of Bioengineering Outside Reviewer for Scott Kofoed, PhD Candidate, May 2000

University of Waterloo, Ontario, Canada

Cooperative Education Career Services, Supervisor for Student Coop Work Term Colin Cheung-Seekit, Systems Engineering Student, January 6-April 26, 1997

The Virtual Anesthesia Machine and the APSF anesthesia machine workbook are being used in at least 350 programs and institutions worldwide. The regularly updated list can be viewed on the Web at: http://www.anest.ufl.edu/~eduweb/vam/vam-institutional-use.doc

Web-based CME course with a maximum of 6 Category 1 credits towards the AMA Physician's Recognition Award (posted April 13, 2004) at <a href="http://vam.anest.ufl.edu/cme/accreditation.html">http://vam.anest.ufl.edu/cme/accreditation.html</a>

# MAINTENANCE OF CERTIFICATION IN ANESTHESIOLOGY (MOCA) SIMULATION SESSIONS

Conducted mock mini-MOCA as part of submission process for ASA endorsement on February 26, 2014

Applied for ASA endorsement multiple times; final submission on March 10, 2014

Obtained ASA endorsement on March 28, 2014

Established MOCA fee schedule, early bird fee, minimum class size, cancellation and refund policies and other deadlines and milestones

Obtained CME accreditation for UF MOCA course on September 23, 2014

Taught MOCA session on Saturday, September 27, 2014

Taught MOCA session on Saturday, October 25, 2014

Taught MOCA session on Sunday, November 16, 2014 to coincide with College of Medicine Alumni Reunion

Taught MOCA session on Saturday, December 6, 2014

Taught MOCA session on Saturday, February 14, 2015

Taught MOCA session on Saturday, April 18, 2015

Taught MOCA session on Saturday, June 20, 2015

Taught MOCA session on Saturday, August 8, 2015

Taught MOCA session on Saturday, September 19, 2015

Taught MOCA session on Saturday, November 11, 2015

Taught MOCA session on Saturday, December 12, 2015

# COMMITTEE APPOINTMENTS AND PROFESSIONAL SERVICE

#### **Current Committee Appointments**

American Institute of Biological Sciences

Medical Simulation Training Program FY10 Scientific Peer Review Committee, 2010 - present

## American Society of Anesthesiologists

ASA Ad Hoc Committee on Screen-Based Simulation; 1/13/16 - present

Committee on Equipment and Facilities, 2008 – present

Anesthesia machine workshop proposal for ASA 2015 meeting submitted under E&F Committee on November 13, 2014

Delegate to 15<sup>th</sup> WFSA World Congress of Anaesthesiologists, Buenos Aires, Argentina, March 25-30, 2012

# Anesthesia Patient Safety Foundation

Committee on Education and Training, 2002 – present

Committee on Technology, 2014 – present

Task Force for Medical Training Device Initiative in Collaboration with Industry, 2014 – present

Judge for APSF's Ellison Pierce award for best Patient Safety scientific exhibit at ASA, October 14, 2012

#### Florida Healthcare Simulation Alliance

Advisory Board member, 2012 – present

# I. Heermann Anesthesia Foundation, Inc.

Board of Trustees, 2004 - present

# University of Florida

**Brain Institute** 

Faculty Advisory Committee for Computing and Information Technology, 1998 - present

Multimedia Equipment and Facilities RFP Evaluation Committee, 1998 – present Distance Learning Council – 2006 – present

## College of Dentistry

R&D collaboration with Dr. Calogero Dolce for a faster and more accurate method of orthodontic bracket placement; patent application being prepared; 2014 - present

# College of Medicine

Member of Faculty Enhancement Opportunity (FEO) committee that reviews FEO applications from COM faculty, 2014 - present

Department of Anesthesiology

Anesthesia Performance Improvement Committee (APIC), 2014 - present

Anesthesia Electronic Medical Records Committee, 2000 – present

Research Committee, 2000 – present

Helped senior faculty member Laurie Davies, MD, in her MOCA PPAI project related to surgical fire prevention in ORs (2014)

Nominated by Dr. Enneking to represent Anesthesiology Department (together with Dr. N. Gravenstein) on the Experiential Learning/Simulation AHC Committee 4/14/2012

UF Clinical and Translational Science Institute

Strategies Work Group, 2011 – present

Consultant to new UF College of Nursing Academic Dean Haddad for restructuring simulation training

Translational Workforce Development writing team for CTSA renewal 2014 - present

#### Academic/Health Science Center

**UFHealth IT** 

in

Collaboration and training of UFHealth IT personnel (Williams) in developing new Virtual Human applications, 2014

## UFHealth Library IT

Collaboration and training of UFHealth Library IT personnel (Norton, David, Richmond)

developing new Virtual Human applications and running of existing VH applications

Simulator Center Task Force, 2003 – present

# UFHealth Surgical Safety Initiative

Helped senior faculty member Laurie Davies, MD, in her MOCA PPAI project related to surgical fire prevention in ORs (2014)

Developing learning objectives for Virtual Human-enabled team training in Wrong Specimen/Blood in Tube (WSIT/WBIT); initiated September 9, 2014

World Federation of Societies of Anaesthesiologists (WFSA)

Advisory Group, April 2012 - present

# **Completed Committee Appointments**

American Society of Anesthesiologists

Facilitator, Subcommittee on Equipment, Monitoring, and Engineering Technology, 1998, 1999, 2002

Committee on Equipment and Facilities

Subcommittee on the Daily Anesthesia Checkout, 2004-2008 – Co-authored new anesthesia machine pre-use check guidelines in 2008 with other task force members

Committee on Simulation Education, October 2006 – 2010

Invited to join ASA Task Force for MOCA 2.0 Online Screen-Based Simulation by its chair Randy Steadman, MD, June 6, 2014

American Society for Testing and Materials

F29.01.09--Anesthesia Workstations Subcommittee, 1993 - 1999

Anesthesia Patient Safety Foundation

Exhibit for ASA 2007 Annual Meeting, October 14-16, 2007

International Meeting on Simulation in Healthcare

IMSH Abstracts: IMSH Research Committee: Technology Innovation Committee: Samsun Lampotang, PhD, Noah Syroid, M (2013-2014)

Physicians' Services Incorporated (PSI) Foundation, Canada Reviewer for proposal for a neurosurgical simulator, September 28, 2012

Society for Technology in Anesthesia

Board of Directors, 2004 - 2007

Co-Chair, Session for Simulation in Anesthesia, STA 1998 Annual Meeting, 1997-1998

Organizing Committee for 1994 STA Annual Meeting, 1993-1994

Working Group on "Experience the Simulators," 1993-1994 (Co-chairman)

Financial Oversight Committee, 1995 - 1997

Scientific Presentation Committee, 1997 – 1997

University of Florida

Distance Education Advisory Committee, 2003-2006

College of Medicine

Department of Anesthesiology

Bain Circuit Committee, 1984-1987

Resident Education/Recruitment Committee

Subcommittee on Training Devices and Simulators, 1994-2000 (Co-chairman)

Office of Research, Technology and Graduate Education

Review Committee for Biomedical Engineering Proposals Submitted to the Interdisciplinary Research Initiative (IRI) Funded by ORTGE, 1996 - 1999 Standing Committee for Opportunity Fund Proposals, 1997 – 1999

World Federation of Societies of Anaesthesiologists (WFSA)
Standing Committee on Safety and Quality of Practice - May 2004 – March 2012

World Health Organization (WHO)/WFSA Global Oximetry (GO) Project, now LifeBox Member of Workgroup on Education and Training, 11/08 – 3/12

# OTHER PROFESSIONAL SERVICE (NON-COMMITTEE)

# **Current Other Professional Service (Non-Committee)**

**UF Process Improvement Projects** 

BIG AIM Project - Participated in establishing multi-departmental process improvement in transfer of patient care from OR to ICU locations, 2009-present

Custom adapter to allow administration of metered dose inhaler contents into anesthesia breathing circuit without having to disconnect elbow connector from endotracheal tube – November 2013 - August 2014

Contributed idea to use GloGerm simulated bacteria deposited on outside of personal protective equipment (PPE) to determine if UFHealth precautions/protocol for Ebola are sufficient to

- prevent contamination on disrobing from a contaminated isolation suit. This idea was adopted with Fluorescein as the marker instead of GloGerm and used in a training video produced by ED Department. October 2014
- Designed, implemented and rolled out a system in close collaboration with Laurie Davies, MD and Clinical Engineering to have each UFHealth anesthesia machine include a 5.0 mm endotracheal tube adapter for use with the auxiliary common gas outlet to comply with Joint Commission Sentinel Event Alert #29 to decrease the risk of surgical fire, 2014
- Put together a goodwill coalition consisting of CSSALT, UF CISE VERG group, UF CTSI, UF Health Nursing, UF Health IT and UF Health Library IT groups to provide a sustainable program for VH-enabled clinical team training. This program is organic and required no funding from UF being totally funded by >\$1.2M of extramural funding from NSF/HCC, NIH/NCATS, BC/BS Florida Blue Foundation, 2014 present
- Suggested adding the TSA warning "If you see something, say something" to patient safety posters describing the AHRQ TeamSTEPPS CUS (Concerned, Uncomfortable, Safety) Speaking Up Protocol to be placed in UFHealth operating rooms and other patient care locations. The rationale is to normalize speaking up in healthcare to non-medical Speaking Up applications that healthcare workers are already familiar with from seeing the signs at airports and now campuses. The suggestion was adopted and implemented, January 31, 2015

# Massachusetts General Hospital

Loan of UF Regional Anesthesia mixed simulator for use by David Edwards, MD for required faculty training for all Massachusetts General Hospital attendings: 2/4/2015, 2/11/2015

# University of Florida

College of Pharmacy, Emerging Pathogens Institute

Collaboration with Robert Huigens, Junior Faculty, College of Pharmacy and Emerging Pathogens Institute, biofilm study on discarded urine drainage systems from urine dependent loop study, 2014 - present

# Department of Anesthesiology

- Through VAM web site, helped the UF Department of Anesthesiology become the first ranked Anesthesiology Department at #6 upon a Google search in "anesthesiology" March 2004 present
- Project coordinator of Virtual Anesthesia Machine (VAM) web site <a href="http://vam.anest.ufl.edu">http://vam.anest.ufl.edu</a>, the #1 listing upon a Google search on "anesthesia machine" since April 1, 2002
- Project coordinator of Virtual Airway Device web site <a href="http://vam.anest.ufl.edu/airwaydevice">http://vam.anest.ufl.edu/airwaydevice</a>, the #1 listing upon a Google search on "airway device" since January 2004
- Designed the UF Virtual Anesthesia Machine web-site that is the top listing since April 1, 2002 in the Internet search engines Google and Yahoo and receives in excess of 200,000 hits per month 1999 present
- Conducted a study in summer 2011 with Gale Danek of Shands Nursing to measure the prevalence of dependent loops in urine drainage systems at UF&Shands Academic Health Center (obtained in-kind support of \$2,080 from CRC scatterbed nurses for this study)
- Modified Aestiva pre-use checklist to include "Verify that your EMR patient is the right

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person", July 6, 2011
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Organized the 8/2/2011 and 8/19/2011 Intra-Osseous Access training for all interested Anesthesiology Department personnel (together with Cindy Le)

Helped Dr. Al Robinson introduce the UF-developed Subclavian Central Venous Access Simulator for training Anesthesiology and Emergency Department residents and faculty August 2011

Exhibited 3 posters at mini-ASA: Schwab et al poster; Robinson et al poster and Lampotang et al poster; October 5, 2011

Process improvement: Conducted a prevalence study of chest drainage systems with undrained dependent loops, October 2011

Process improvement – at morning conference, suggested using 4 or 5 ml syringe, instead of 12 ml syringe, in shrink-wrapped airway tray to discourage endotracheal tube cuff over-inflation, October 7, 2011

Designed and posted online via SurveyMonkey an APSF poll on urine drainage management, November 3, 2011

Attended the I/ITSEC Interservice/Industry Training Simulation & Education Conference, Orlando, FL; November 29, 30, 2011

Initiated in-situ code simulation team training in PACU (started this ongoing exercise in January 2012 with Dr. Wendling as project leader)

Submitted application for ASA/ABA endorsement of UF simulation program 3/2/12

Voting Delegate of the American Society of Anesthesiologists at the First General Assembly of the World Federation of Societies of Anaesthesiologists, 15<sup>th</sup> World Congress of Anaesthesiologists, Buenos Aires, Argentina, March 25, 2012

Voting Delegate of the American Society of Anesthesiologists at the Second General Assembly of the World Federation of Societies of Anaesthesiologists, 15<sup>th</sup> World Congress of Anaesthesiologists, Buenos Aires, Argentina, March 27, 2012

Review of upgraded Avance for Department as replacement for Aestivas, April 10, 2012 Review of HeartWorks, a TEE and TTE cardiac simulator for Larry Caruso, MD/Department, April 12, 2012

Attended University of Florida Department of Anesthesiology Safe Analgesia Retreat, May 21, 2012

Set specifications and selection criteria for new University of Florida anesthesia machine by invitation from Dietrich Gravenstein, MD and David Paulus, MD, May 22, 2012

Member of Inaugural Class for University of Florida Clinical and Translational Science Institute Academy of Research Excellence for Clinical Research May 23, 2012

CSSALT provided two 3D-printer-produced spines in Permagel simulators for RAP Regional Anesthesia workshops at the UF Veterinary School on May 19, 2012 and June 2, 2012

Demonstrations of simulation research to resident applicants: 10/4/2011; 10/11/2011; 10/25/2011; 11/1/2011; 11/8/2011; 12/6/2011; 12/13/2011; 1/10/2012; 1/17/2012; 1/22/2012

Demonstrations of simulation research to medical school applicants: 12/16/2011;

Supervisor for full-time employees:

David E. Lizdas, BSME, IT Expert, 2000 - now

Isaac Luria, MS, Simulation Engineer, 2009 – July 20, 2012

Greg Goldenhersh, MD, Simulation Engineer, July 1, 2012 – 2013

Drew Gonsalves, MS, Simulation Engineer, May 2013 - present

## Department of BioMedical Engineering

Obtained affiliation as affiliate faculty of the UF Biomedical Engineering Department on December 16, 2011

# Department of Medicine, Division of Cardiology

Training of UF Cardiology faculty and fellows in subclavian venous access using the UF mixed reality simulator (at the request of Dr. Flynn) -4/24/2012 and 4/27/2012

# Department of Nephrology

In close collaboration with Dr. Ed Ross, developed a proof of concept simulation of the BBraun Diapact CVVH machine that was exhibited at BBraun booth at the Nov 2003 ASN meeting in San Diego - August 2003 - 2008

# Department of Plastic Surgery

Completed an animation for healing of deep wounds with wound dermal paste, growth factors and micro-irrigation for Adam Katz, MD, UF Plastic Surgery on June 27, 2012

# Department of Surgery

Collaboration with Ivan Zendejas, MD and Nik Gravenstein, MD on a smoke evacuation system during laparoscopic surgery, 2014 - present

#### Department of Urology

Collaboration with Vice-Chair of Urology Department to develop an enhanced method of ultrasound-guided sampling according to the sextant pattern during manual prostate biopsy procedures, 2014 – present

# Partnership in Global Learning

Simulation demonstrations and negotiations with IBM and Cisco Learning Institute-

# **Shands Nursing**

Meeting with Irene Alexaitis and others on Interdisciplinary UF & Shands Simulation Planning Meeting May 30, 2012

Updated simulation equipment inventory at the UF&Shands Academic Health Center at the request of Irene Alexaitis; June 5, 2012

Kick-off meeting with Christine Brinza and Michelle Brunges to mentor on proposal to BC/BS Florida Blue Foundation for mini-grant to use simulation to train against wrong blood/sample in tube October 1, 2013

#### UF&Shands.org

Arranged for links from new ufandshands.org web site to http://simulation.health.ufl.edu

6/25/12

Negotiations for CSSALT to become a regional simulation training center for the Florida Healthcare Simulation Alliance, 2014

Completing the application process for CSSALT to become an official University of Florida center

Recruited speakers and organized 6 Safety & Simulation Seminars as part of the UF CTSI Simulation Core activities

4/20/15 5/11/15 6/15/15 7/27/15 9/17/15

10/15/15

# **Completed Other Professional Service (Non-Committee)**

# University of Central Florida

Evaluation of Juan Cendan, MD for promotion to Professor at UCF College of Medicine, July 26, 2014

Datex-Ohmeda, Madison, Wisconsin. Clinical interaction. April 19, 2002

# **Duke University**

External reviewer for promotion of Jeffrey Marc Taekman, MD to the rank of Professor of Anesthesiology submitted May 21, 2014

International Meeting on Simulation in Healthcare 2014: Technology Abstract co-chair (with Noah Syroid) and reviewer for 30 abstracts for IMSH Scientific Contents Committee and led the scientific review process of abstracts submitted to the Technology Innovation Track at IMSH, July – October 2013

Macromedia, San Francisco, California. The Virtual Anesthesia Machine project has been selected as a beta site for evaluating new releases of Macromedia Director, the authoring package used to create the Virtual Anesthesia Machine (VAM). October 2, 2003

# Massachusetts General Hospital

Trial of UF Regional Anesthesia mixed simulator at MGH by David Edwards, MD, May 12 – 17, 2014

# MaxTec, Salt Lake City, Utah

Development of an indicator of adequate face mask seal during bag valve mask (BVM) Ventilation based on the amount of exhaled gas passing through the indicator placed at the exhalation port of a self-inflating resuscitation "Ambu" bag – based on Lampotang S, Lizdas DE, Gravenstein N, Robicsek S: Audible indication of exhalation increases delivered tidal volume during bag valve mask ventilation of a patient simulator. Anesth Analg 102:168-171, 2006, 2010 - present

Simulator-based evaluation of the MaxTec FloCap indicator of adequate face mask seal during BVM, 2014

# Northwestern University

Letter of evaluation for Ling Qun Hu, MD Northwestern University Feinberg School of Medicine for promotion from Assistant Professor to Clinical Associate

Professor,

submitted September 14, 2012

Letter of Recommendation for Lingqun Hu, MD, Associate Professor of Anesthesiology, Northwestern University for membership in Feinberg Academy of Medical

Educators

(FAME), submitted April 3, 2014

# Partnership in Global Learning

Helped organize PGL workshop on E-Learning Objects and Systems, Orlando, FL, June 3-4, 2004

# UFHealth Learning Health System

Applied for and obtained accreditation for 1.5 credits hours of Continuing Nursing Education for VH-enabled training of UFHealth Nurses in Speaking Up, September 20, 2013 Presentation of NSF funded, VH-enabled OR Nurses training project to UF Health Quality Board meeting, September 25, 2013

# University of Florida

Office of the Vice President for Research

Reviewer for faculty complaint regarding processing of patent application, 1995

#### Center for Safety, Simulation & Advanced Learning Technologies

Attended and represented UF at the 5/3/14 Simulation Education Network meeting in Chicago, May 3, 2014

#### Department of Anesthesiology

Successfully defended registered copyright on VAM/VFGS against infringement by Drager Virtual Primus simulation, May 2004

Engineering Paper Club, Chairman, 1993 – 1999

In collaboration with Michael Banner, PhD, and Paul Blanch, RRT, designed, built and licensed the minimalist Max transport ventilator to Hamilton Medical, Switzerland

Collected unused and duplicate textbooks for donation to the Association of Anaesthesiologists of Mauritius, 1993

Evaluation of Adam Wendling, MD for promotion to Associate Professor, August 9, 2013 Screen-based simulation of Operating Room Electrical Safety delivered to Gordon Gibby, MD and Mark Rice, MD for ASA 2013 panel with MOCA Safety credits, August 13, 2013

#### Department of Physics

Designed and implemented a web simulation of elastic and inelastic particle collisions,

December 2003

# Department of Anthropology

At the request of Dr. Karen Holbrook, I consulted on the design of a software package "ETHNOPOP," for simulating problems in anthropology and epidemiology, March 1998

Supported translation to Chinese of the landing pages for the spinal anesthesia simulation and CO2 absorption in a circle system and to Spanish for the alveolar gas equation interactive model, 2007-2008

Created and launched the UF Simulation Faculty Learning Community and organized twelve seminars that were also video-conferenced to Jacksonville Campus, 2008-2009

UF CoM Office of Medical Education. Successfully nominated Lou Ann Cooper, PhD to a courtesy appointment in Anesthesiology, January 14, 2014

University Health Science Center Instructional Support Committee lecture, "Update on simulation technology and education at UF HSC, February 20, 2008

#### University of North Florida

External reviewer for promotion of Alexandra Schönning to Full Professor in the Department of Mechanical Engineering at the University of North Florida. September 12, 2013

# University of Ottawa

External reviewer for promotion of Viren Naik, MD to Full Professor, Department of Anaesthesia, Faculty of Medicine, University of Ottawa, Canada, December 23, 2013

Graduated from foundational semester-long class of UF CTSI Academy of Research Excellence, November 1, 2012

Attended week-long Harvard Center for Medical Simulation Comprehensive Simulation Instructor course, April 7- 11, 2014

Attended Harvard Center for Medical Simulation Graduate Simulation Instructor course, May 12 – 17, 2014

# PUBLICITY FOR VIRTUAL ANESTHESIA MACHINE (VAM) AND DEPARTMENT OF ANESTHESIOLOGY

Featured on October Edition of E-newsletter for Outpatient Surgery at URL http://www.outpatientsurgery.net/newsletter/10-21-02.htm

University of Florida Points of Pride, January 30, 2002 http://www.pr.ufl.edu/pointsofpride/2002JAN30.pdf

Featured as lead story on National Center for Simulation web site at URL: <a href="http://www.simulationinformation.com/index2.html">http://www.simulationinformation.com/index2.html</a> June 17, 2003

Featured on Shands.org/health/heartbeat/affiliates.htm, approximately 70 national affiliates, January 5, 2004

Cooling football pads on trial at UF, Gainesville Sun, January 27, 2004. (Based on interview with inventors, Nikolaus Gravenstein and Sem Lampotang)

Interview with Mid-Florida Public Radio (FM 89.1) on the air-cooled football pads, which aired August 23, 2004

Cooling football pads, WCJB-TV 5:30 pm news on August 26, 2004.

Featured in the Winter 2004 edition of the APSF Newsletter: APSF Awards 4 Grants, <a href="http://www.aspf.org/resource\_center/newsletter/2004/winter/06apsf\_awards\_4.htm">http://www.aspf.org/resource\_center/newsletter/2004/winter/06apsf\_awards\_4.htm</a>
Raths D: VR to OR: Can online learning and virtual reality simulators revolutionize medical training? Learning Circuits. Online <a href="http://www.learningcircuits.org/2006/June/raths.htm">http://www.learningcircuits.org/2006/June/raths.htm</a>

<u>http://www.ihe-online.com/newsletter/index19.1.html</u>
Web page – Volume 2, Issue Number 6 of IHE (International Hospital Equipment & Solutions)

http://news.health.ufl.edu/2011/17459/colleges/college-of-medicine/residents-test-new-simulator-for-safety/ Web page published September 14, 2011

<a href="http://vam.anest.ufl.edu/intro.html">http://vam.anest.ufl.edu/intro.html</a>Publication distributed to all medical school deans;implemented at the request of UF HSC News Office 10/21/2011

Goldberg ME: 2011 Scientific and Educational Exhibit Award Winners. ASA Newsletter Volume 76, Number 2, February 2012 issue; pages 42-43, 2012 – can also be viewed at <a href="http://viewer.zmags.com/publication/1da72863#/1da72863/44">http://viewer.zmags.com/publication/1da72863#/1da72863/44</a>

2013 Scientific and Educational Exhibit Award Winners Anesthesia Patient Safety Foundation Newsletter Winter 2013- 14 issue:
<a href="http://www.apsf.org/newsletters/html/2014/winter/10\_exhibitaward.htm">http://www.apsf.org/newsletters/html/2014/winter/10\_exhibitaward.htm</a>

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Gravenstein JS, Good ML, Lampotang S, Carovano RG: The Gainesville Anesthesia Simulator, in Menzel H (ed): Konzepte zur Risikominderung in der Anasthesiologie. Munchen, W. Zuckschwerdt Verlag, pp 107-117, 1993

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Liem EB, Lampotang S: Anesthesia machine malfunctions, in Lobato EB, Gravenstein N, Kirby RR (eds): Complications in Anesthesiology, 3<sup>rd</sup> ed. Philadelphia, Lippincott Williams & Wilkins, pp 800-818, 2008

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## **Editorials and Invited Articles**

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#### NONREFEREED PUBLICATIONS

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Lampotang S: Alveolar gas equation (AGE) simulations (simplified and complete versions of AGE) added 3/27/08

Lampotang S: Spinal anesthesia simulation added 9/27/07

Lampotang S: Simulation of generic piston ventilator anesthesia machine with PSV added 8/15/07

Lampotang S: Comparative simulation of propofol vs. fospropofol added 8/13/07

Lampotang S, Lizdas DE, Robinson A, Ihnatsenka B, Gravenstein N: Mixed Simulators: Seamlessly Integrating Physical and Virtual Simulation for Training in Procedural Skills and Safety. *Anesthesia Patient Safety Foundation Newsletter*, 29:1, June 2014 <a href="http://www.apsf.org/newsletters/html/2014/June/pdf/spring2014.pdf">http://www.apsf.org/newsletters/html/2014/June/pdf/spring2014.pdf</a>

#### **Electronic Publications/Simulations**

Simulated Anesthesia Application Phase I delivered to Organon on June 29, 2007

Simulated Anesthesia Application Phase IIA delivered to Organon USA 1/10/08

Simulated Anesthesia Application Phase IIB delivered to Schering Plough 7/7/08

Preliminary version of ChloraPrep simulation completed on 8/11/2008 with exhibit at Enturia National sales meeting on 8/12/2008

Completed localization of SAA Phase IIB for United Kingdom market for use at AAGBI (Association of Anaesthetists of Great Britain and Ireland) meeting - 8/2008

Completed video of routine rocuronium reversal with sugammadex for global launch of the UF Simulated Anesthesia Application – delivered 9/22/08

Completed the Augmented Drager Apollo simulation, a mixed reality simulation of the Drager Apollo anesthesia workstation, 10/2008

Completed the Augmented Drager Primus simulation, a mixed reality simulation of the Drager Primus anesthesia workstation, 11/2008

ChloraPrep Simulation for the iPad; released to CareFusion on June 29, 2012

Completed mixed reality simulation of Central Venous Access – 2012

Completed mixed reality simulation of regional anesthesia – 2013

# **REVIEWS BY OTHERS**

Batich CD: Research cover story: this guy is no dummy. Florida Engineer, Fall 1997, pp 16-17, 1997 (review of Dr. Lampotang's work on the Human Patient Simulator)

Phillips WM: The competitive edge in the information age. Florida Engineer, Fall 1997, p 3, 1997 (mentions the Human Patient Simulator)

Brettenfeld J, Bartholomaus U: Stan darf nicht sterben (Stan must not die). Focus 19(4):125-128, 1998

Kristen Philipkoski. Drug-Testing dummies. Wired News. <a href="http://www.wired.com/news/technology/0,1282,15787,00.html">http://www.wired.com/news/technology/0,1282,15787,00.html</a> October 23, 1998

Marsha Walton. Simulator allows medical students to train without risks. Cable News Network (CNN) news release http://www.cnn.com/HEALTH/9903/14/patient.simulator/ March 14, 1999 Marsha Walton. Chronic 'patient' makes students breathe easier. http://www.cnn.com/TECH/computing/9903/04/t t/patient.sim/ March 1999

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White V: UF faculty develop 'virtual anesthesia machine.' University of Florida Press Release. (http://www.napa.ufl.edu/2002news/webanesthesia.htm)

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Unsolicited comments by users of the Virtual Anesthesia Machine are on the Web at: <a href="http://www.anest.ufl.edu/~eduweb/vam/vam-user-comments.doc">http://www.anest.ufl.edu/~eduweb/vam/vam-user-comments.doc</a>

Publicity for the Virtual Anesthesia Machine in the APSF Newsletter, 2003-2004. <a href="http://www.apsf.org/loadurl/loadurl.php?www.gasnet.org/societies/apsf/newsletter/2003/fall/07workbook.htm">http://www.apsf.org/loadurl/loadurl.php?www.gasnet.org/societies/apsf/newsletter/2003/fall/07workbook.htm</a>

Game + Learning = Free Coffee. The Post, October 2010, pg 6

Do you believe in magic? The Post, December 09-January 10, 2010, pg. 6

Videotaped interview with Scott Blades as part of UF video designed to inspire new UF hires during UF employee orientation to illustrate the breadth and impact of UF research

UF Health News Release DoD Grant on August 20, 2014: <a href="https://ufhealth.org/news/2014/uf-developing-mixed-reality-simulators-training-treatment-injured-soldiers">https://ufhealth.org/news/2014/uf-developing-mixed-reality-simulators-training-treatment-injured-soldiers</a>

UF News Release DoD Grant Video: https://www.youtube.com/watch?v=sMxH1lprc10

Gainesville Sun article DoD grant:

http://www.gainesville.com/article/20140918/ARTICLES/140919559/0/search?p=1&tc=pg

NPR-Affiliate WUFT radio station on September 9, 2014: <a href="http://www.wuft.org/news/2014/09/16/uf-researchers-develop-mixed-reality-training-technology-for-military/">http://www.wuft.org/news/2014/09/16/uf-researchers-develop-mixed-reality-training-technology-for-military/</a>

Jacksonville TV: Medics preparing for the battlefield <a href="http://www.actionnewsjax.com/news/news/local/medics-preparing-battlefield/njCnm/">http://www.actionnewsjax.com/news/news/news/local/medics-preparing-battlefield/njCnm/</a>

#### REVIEWS BY OTHERS IN PEER-REVIEWED JOURNALS

Larkin M: Anaesthesia in action: Virtual anesthesia machine. Lancet 359(9312), 2002

Olympio MA (reviewer): The virtual anesthesia machine. Anesthesiology 96:1281, 2002

Doyle DJ (reviewer): Web Site Review: "The Virtual Anesthesia Machine" (Version 8.32). Can J Anesth 50:206-207, 2003

Gaiser RR (Reviewer): Lampotang S, Lizdas D, Liem EB, Gravenstein JS: The Anesthesia Patient Safety Foundation Anesthesia Machine Workbook. Anesth Analg 97:929-930, 2003

#### PAPERS SUBMITTED OR IN PREPARATION

#### In Preparation

## Submitted

Gonsalves D, Gravenstein N, Lampotang S: Novel Device for Preventing Air Embolus When Using Pressurizing Cuffs with Air-Containing Intravenous Bags, Technical Report manuscript submitted to Anesthesia & Analgesia on 8/21/15

Mohammad S, Gravenstein N, Gonsalves D, Vasilopoulos T, Lampotang S: Higher Fresh Gas Flow Rates Decrease Tidal Volume during Pressure Control Ventilation; submitted to Anesthesia & Analgesia on 11/30/15

Lampotang S, Lizdas D, Quarles JP, Gravenstein N: Propofol ESC EC50 at Loss of Consciousness Differs Among Indians, Blacks, Chinese And Caucasians. World Congress of Anesthesiologists (WCA) 2016 abstract WCA16-ABS-1219 submitted on 12/27/15

Edwards DA, Vazquez R, Lizdas DE, Lampotang S: A mixed reality simulator augmented with real-time 3D visualization helps develop a modified technique for accessing the thoracic epidural space; abstract submitted to American Society of Regional Anesthesia on 12/31/15

# Accepted

Robb A, Kleinsmith A, Cordar A, White C, Lampotang S, Wendling A, Lok B: Do Variations in Agency Indirectly Affect Behavior with Others? An Analysis of Gaze Behavior. Visualization and Computer Graphics, IEEE Transactions on. 2016 In Press

Robb A, Cordar C, White C, Lampotang S, Wendling A, Lok B: Teaming Up With Virtual Humans: How Other People Change Our Perceptions of and Behavior with Virtual Teammates. IEEE Virtual Reality 2015 (accepted)

White C, Chuah JH, Robb A, Lok B, Lampotang S, Lizdas D, Martindale J, Pi G, Wendling A: A Critical Incident Scenario with Virtual Humans. Journal of Continuing Education in the Health Professions (*accepted with revision 1/30/2015*)

# Submitted Pending Review

<u>Lampotang S, Lizdas DE, Derendorf H, Gravenstein N, Lok B, Quarles JP: Race-Specific Pharmacodynamics Model of Propofol-Induced Loss of Consciousness; submitted to Journal of Clinical Pharmacology on 12/17/15; review received on 1/11/16; revised manuscript submitted 1/20/16</u>

#### Submitted and Declined

Zheng G, Gravenstein N, Morey TE, Ben-David K, Lampotang S: Effects of Heliox on Intraoperative Respiratory Management for a Patient Undergoing Laparoscopic Bariatric Surgery; submitted to Anesthesia & Analgesia on October 20, 2011, (declined)

Late-Breaking ASA abstract: Lampotang S, Luria I, Schwab W, Cooper LA, Lizdas D, Gravenstein N: Automated fresh gas flow recommendations alter isoflurane consumption in a simulated anesthetic submitted August 31, 2012 (declined); now published as A&A peerreviewed paper

Lampotang S, Lampotang K, Lizdas DE, Schwab WK, Gravenstein N: Fluid-Filled Dependent Loops in Chest Drainage Systems Attenuate Set Vacuum Level and Impede Lung Model Re-Inflation. Submitted to Anesthesia & Analgesia, (declined)

Jason Jendrusch, Samsun Lampotang, David Lizdas, Nikolaus Gravenstein, Benjamin Lok, Dwayne Ham, John Quarles: Learning about Variability through Simulation: Variable, Model-Driven Virtual Humans and Abstract Visualization, submitted to IEEE VR 2013, (declined); now published as MMVR paper

Lampotang S, Jendrusch J, Lizdas DE, Gravenstein N, Ham D, Lok B, Quarles JP: A mixed simulator of ethnic variability to propofol during sedation and analgesia; submitted as an ASA abstract April 2, 2013 (*declined*)

Late-Breaking ASA abstract on IV pump alarm management submitted: Fiastro A, Goldenhersh G, Lizdas D, Shaik S, Gravenstein N, Lampotang S: Empowering patients to reduce IV infusion pump alarm incidence, submitted August 23, 2013 (declined)

Lampotang S, Quarles JP, Lizdas DE, Cooper LA, Gravenstein N: Personalized anesthesia: Is patient race considered during simulated propofol sedation? submitted August 31, 2013 (declined)

Robb A, Cordar A, White C, Lampotang S, Wendling A, Lok B: Towards Illusory Realism: Reconsidering Assumptions about Social Presence and Virtual Agents" ACM SIGCHI. 2015. (declined)

Cordar C, Robb A, Wendling A, Lampotang S, White C, Lok B: Consistency is Key: The Advantages of Mixed-Reality Virtual Humans as Teammates for Medical Team Training. Long paper submitted to VRST 2014 meeting (*declined*)

#### PAPERS AND LECTURES PRESENTED

Samsun Lampotang, Ph.D.

The cost of wasted anesthetics. 65th Congress. International Anesthesia Research Society, San Antonio, Texas, March 8-12, 1991

Preventing risk and solving problems in anesthesia using hands-on simulation. Guest Lecturer. University of Florida, Department of Anesthesiology, Anesthesia Patient Safety Foundation, Anesthesiology Alumni Association of Florida, Inc., and Ohmeda Anesthesia Systems, Gainesville, Florida, November 30-December 1, 1991

Anesthesia delivery systems: past, present (and future?). Visiting Lecturer Series. Massachusetts General Hospital, Boston, Massachusetts, May 15, 1992

A review of anesthesia delivery system modifications and designs. Guest Lecturer. Department of Anesthesiology, University of Utah, Salt Lake City, Utah, July 1, 1992

FDA recommended anesthesia apparatus checkout procedure. Annual Meeting. Florida Society of Anesthesiology Technologists and Technicians, Gainesville, Florida, September 26-27, 1992

Airway heating and humidification (October 28). Gainesville Anesthesia Course for Sales Representatives. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, October 26-28, 1992

Anesthesiology teaching conference **and** Pre-use check, use and operation of the anesthesia machine (January 7); Malfunctions of the anesthesia equipment (January 10); Pre-use check, use, and operation of the anesthesia machine (October 5); **and** Malfunctions of the anesthesia equipment (October 9). Anesthesiology Rotation for Dental General Practice Residents. University of Florida College of Medicine, Gainesville, Florida, January-October 1992

Airway heating and humidification, temperature monitoring. Gainesville Anesthesia Course for Sales Representatives. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, March 15-17, 1993; March 29-31, 1993; April 27, 1993, June 16, 1993, June 23, 1993, October 6, 1993, and November 15-17, 1993

The Gainesville Anesthesia Simulator. Guest Speaker. Department of Mechanical and Aerospace Engineering Colloquium, University of Central Florida, Orlando, Florida, February 23, 1994

A device to simulate thumb twitch response to ulnar nerve stimulation in anesthetized patients (March 30). 14th Medical Monitoring Technology Conference. Ohio State University, Department of Anesthesiology, Vail, Colorado, March 28-31, 1994

Airway heating and humidification, temperature monitoring. Gainesville Anesthesia Course for Sales Representatives. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, September 12-14, 1994

The anesthesia simulator **and** The FDA pre-use checklist for the anesthesia machine (workshop). 5th Annual Meeting. Florida Society of Anesthesia Technicians and Technologists, Gainesville, Florida, September 24, 1994

The human patient simulator (April 19). Industry Early Bird Seminar. 42nd Annual Meeting. Japanese Society of Anesthesiologists, Hamamatsu, Japan, April 19-21, 1995

Concepts and terminology of anesthesia simulation; The University of Florida/Loral human patient simulator (lecture and workshop); **and** Simulators for anesthesia crisis management: training in the 21st century (panelist). 42nd Annual Meeting. Japanese Society of Anesthesiologists, Hamamatsu, Japan, April 19-21, 1995

The University of Florida human patient simulator. Visiting Professor. Hokkaido University School of Medicine, Sapporo, Japan, April 24, 1995

The University of Florida human patient simulator. Visiting Professor. Sapporo Medical College, Sapporo, Japan, April 24, 1995

Brief overview of the GRADS system **and** Update on the GRADS investigation (June 20). Gainesville Recirculating Anesthesia Delivery System (GRADS) Review, Ohmeda, Madison, Wisconsin, June 20, 1995

Machine faults using the simulator, (given 2 times, October 21). Annual Meeting. American Society of Anesthesiology Technicians and Technologists, Atlanta, Georgia, October 21, 1995

A clinical lung classification system. Grand Rounds Lecture. Shands Hospital at the University of Florida, Surgical Intensive Care Unit, Gainesville, Florida, March 5, 1996

Potential applications of signal processing in anesthesiology. Computational Neuroengineering Laboratory Seminar. University of Florida College of Engineering, Department of Electrical Engineering, Gainesville, Florida, March 6, 1996

The uses of the anesthesia simulator (April 15); Tidal volume, fresh gas flow and simulated carbon dioxide rebreathing (April 16); **and** A simulator study: monitoring for safety, workshop. 11th World Congress of Anaesthesiologists. Australian Society of Anaesthetists and the World Federation of Societies of Anaesthesiology, Sydney, Australia, April 14-20, 1996

Simulator-based usability study of a pre-production anesthesia record keeper **and** Simulator applications at the University of Florida, poster presentation (June 1). Conference on Simulators in Anesthesiology Education. University of Rochester School of Medicine and Dentistry, Rochester, New York, May 31-June 2, 1996

Ventilator performance without a bellows: an explanation (October 21). Annual Meeting. American Society of Anesthesiologists, New Orleans, Louisiana, October 21-24, 1996

A computer model of a linearized two-compartment lung and distribution of ventilation during mechanical ventilation. Annual Meeting. Society for Technology in Anesthesia, Fort Lauderdale, Florida, January 16-18, 1997

A plastic fiberoptic imaging stylet; An ICP model for the human patient simulator; Moderator for Scientific Posters and Discussion; ICP model integrated to an HPS running the ACLS megacode training, demonstration; **and** The ICP model as a stand-alone training device, demonstration. 1998 Annual Meeting. Society for Technology in Anesthesia, January 15-17, 1998

Simulated faults in the anesthesia machine using an anesthesia simulator (workshop) (August 5) **and** Failures in the anesthesia machine and their consequences (August 6). Visiting Professor. University of North Carolina, Chapel Hill, Department of Anesthesiology, Chapel Hill, North Carolina, August 5-6, 1998

Cerebral blood flow in a simulated brain. Visiting Professor. University of Toronto, Toronto General Hospital, Toronto, Ontario, Canada, September 25, 1998

Simulator workshop (SjVO2 monitoring). Society for Neuroanesthesia and Critical Care, Orlando, Florida, October 16, 1998

A plastic optical fiber imaging stylet: mechanical design and preliminary experience (October 19); Facilitator, Equipment monitoring and engineering technology—airway and miscellaneous **and** A continuous respiratory rate monitor derived from the optoplethysmogram of a pulse oximeter: clinical evaluation (October 20). Annual Meeting. American Society of Anesthesiologists, Orlando, Florida, October 17-21, 1998

The Human Patient Simulator (October 31). Visiting Professor. Department of Anesthesiology, Queen Mary Hospital, Hong Kong University, Hong Kong, October 31, 1998

Design, implementation and bench evaluation of a system for automatic synchronization of chest radiographs with the inspiratory pause. 20<sup>th</sup> Annual International Conference. IEEE Engineering in Medicine and Biology Society, Hong Kong, October 29-November 1, 1998

Human Patient Simulator Sessions (workshops) (November 22 **and** 23). Critical Care and Emergency Medicine, 1998. University of Florida, Department of Anesthesiology, Division of Critical Care Medicine, Lake Buena Vista, Florida, November 21-25, 1998

Synchronization of chest x-ray imaging with peak lung inflation; Integration of virtual reality with physical simulation; **and** Virtual reality and METI simulator, workshop (January 22); **and** Virtual reality and METI simulator (January 23). Annual Meeting. Society for Technology in Anesthesia, San Diego, California, January 22-23, 1999

A device to synchronize x-ray beam exposure with peak lung inflation (May 17). Focus Group. Novametrix Medical Systems, Inc, Yale University, New Haven, Connecticut, May 17, 1999

Facilitator: Hemodynamic monitoring poster session (October 11). Annual Meeting. American Society of Anesthesiologists, Dallas, Texas, October 9-13, 1999

The fiberoptic imaging stylet: a new approach for intubation and management of the airway. Mallinckrodt, St. Louis, Missouri, October 26, 1999

Respiratory rate estimation from the optoplethysmogram of a pulse oximeter. Guest Speaker. Novametrix Medical Systems, Incorporated, Wallingford, Connecticut, November 18, 1999

Automatic synchronization of x-ray beam exposure with peak lung inflation during chest radiography. Visiting Professor. Department of Radiology, St. Raphael Hospital, New Haven, Connecticut, November 18, 1999

Automatic synchronization of x-ray beam exposure with peak lung inflation during chest radiography: focus group. Visiting Professor. Department of Anesthesiology, State University of New York, Stony Brook, New York, December 2, 1999

Applications of technology to education of health care personnel. Health Care Issues Day—The Dynamic Health Care Team: 2000 and Beyond. University of Florida College of Medicine, Gainesville, Florida, April 5, 2000

Introduction to simulation. Visiting Professor. University of Toronto, St. Michaels Hospital, Toronto, Canada, August 23, 2000

Panelist, Developing educational software for anesthesia: Web-based solution at the University of Florida. XXI Annual Meeting. Computers in Anesthesia, Monterey, California, October 18-21, 2000

Preliminary experience with a Web-based educational simulation of an anesthesia machine, **and** A model-based computer simulation of gas flows inside the anesthesia machine. Annual Meeting. Society for Technology in Anesthesia, Scottsdale, Arizona, January 12, 2001

Innovations in Education and Technology, The virtual anesthesia machine, panelist. Annual Meeting. Society for Education in Anesthesia, Cleveland, Ohio, June 2-4, 2001

A model based computer simulation of anesthesia machine gas flows **and** Detecting and troubleshooting malfunctions in anesthesia delivery systems. Annual Meeting. American Society of Anesthesiologists, New Orleans, Louisiana, October 13-17, 2001

Design and implementation of a Web-based simulation for a new anesthesia workstation. Annual Meeting. Society for Technology in Anesthesia, Santa Clara, California, January 9-12, 2002

Web-based educational animation of an anesthesia machine. Research Day. University of Florida College of Medicine, Gainesville, Florida, April 18, 2002

The virtual anesthesia machine. 2<sup>nd</sup> Annual Medical Education Week. University of Florida McKnight Brain Institute, Gainesville, Florida, April 15, 2002

Engineering applications in the human patient simulator. IDEAS Workshop. McKnight Brain Institute, University of Florida, Gainesville, Florida, July 1, 2002

Virtual anesthesia machine (VAM), round-table presentation. Visiting Professor. Department of Anesthesiology, Nanjing Medical University, Nanjing, China, September 12, 2002

Virtual anesthesia machine (VAM) **and** The difficult airway, workshop. Visiting Professor. Jiangsu Province Hospital, Nanjing, China, September 13, 2002

Virtual anesthesia machine (VAM). Annual Meeting. Chinese Society of Anesthesiologists, Nanjing China, September 15, 2002

Web-based interactive simulation of an anesthesia machine **and** Veterinary use of a free web-based, interactive anesthesia machine simulation (October 11). Annual Meeting. American College of Veterinary Anesthesiologists, Orlando, Florida, October 10-11, 2002

The virtual reality anesthesia machine. Annual Meeting. American Society of Anesthesia Technologists and Technicians. Orlando, Florida, October 12, 2002

Anesthesia machine in-service to anesthesia technicians using the Virtual Anesthesia Machine. Shands Hospital at the University of Florida, Gainesville, Florida, November 21, 2002

The anesthesia machine unveiled **and** Simulation and web-based learning in medical education, grand rounds. Visiting Professor. University of California Davis Medical Center, Sacramento, California, December 9-11, 2002

The Virtual Anesthesia Machine: An educational experiment combining web simulation and philanthropy. 14<sup>th</sup> International Conference on College Teaching and Learning, Jacksonville, Florida, April 4, 2003

The Virtual Anesthesia Machine: A Web Experiment in Educational Simulation and Philanthropy. Celebration of Research. University of Florida College of Medicine, Gainesville, Florida, April 11, 2003

The Spanish Virtual Anesthesia Machine: Universidad Veracruzana, Hospital Escuela de Ginecologia y Obstetricia, Veracruz, Mexico, July 18, 2003

Lampotang S, Lizdas D, Liem EB, Nyland ME, Gravenstein N: The Virtual Anesthesia Machine: An experiment in sustainable philanthropic education over the Web. Poster presentation, American Society of Anesthesiologists meeting, Moscone Convention Center, San

Francisco, October 14, 2003

The Virtual Anesthesia Machine. Visiting Professor. University of Miami/Jackson Memorial Hospital, Miami, Florida, November 19, 2003

Lampotang S, Lizdas D, Liem EB, Gravenstein JS: Internationalizing a free anesthesia machine simulation and workbook. World Congress of Anaesthesiology. Paris, France, April 18-23, 2004

Workshop Organizer. Workshop on E-Learning Objects and Systems. Partnership in Global Learning, Orlando, Florida, June 3-4, 2004

The Human Patient Simulator, workshop *delivered in French* (April 21 and 22); the Virtual Anesthesia Machine (demonstration) (April 21 and 22); and Internationalizing a free anesthesia machine simulation (April 19). Annual Meeting. World Congress of Anesthesiology, Paris, France, April 18-23, 2004

Keynote lecture: The Developing Frontier of Simulation in Anesthesiology Education and Training at the Chinese Society of Anesthesiologists annual meeting's Satellite Symposium on The Application and Implication of Modern Medical Simulation for Anesthesiology, Jin Guan Hotel, Beijing, China, September 10, 2004

Chinese Society of Anesthesiologists annual meeting, Chinese Virtual Anesthesia Machine Simulation and Workbook, Top-City International Conference Center, Beijing, China, September 13, 2004

Lampotang S, Paulus DA, Gravenstein N: F<sub>D</sub>O<sub>2</sub> accuracy when supplying nasal cannulae from common gas outlets. Poster presentation, American Society of Anesthesiologists meeting, Las Vegas, October 26, 2004

Temperature biophysics and football. NFL Headquarters, New York, New York, November 2, 2004

The Virtual Anesthesia Machine. Internationalization Seminar. University of Florida International Center, Gainesville, Florida, November 15, 2004

Faculty IT showcase organized by University of Florida Office of Academic Technology, "Transparent Reality Simulation as an e-Learning Tool", Reitz Union, November 16, 2004

Show and share session, "The Virtual Anesthesia Machine". Annual Meeting. Society for Technology in Anesthesia, Miami, Florida, Friday, January 14, 2005

Temperature biophysics and football pads. 2005 Annual Meeting. National Football League Equipment Managers, Disney Boardwalk Resort, Orlando, Florida, March 7, 2005

Anesthesia machine pre-use check. Annual Meeting. Florida Society of Anesthesiologists, The Breakers, Palm Beach, Florida, June 25, 2005

Transparent reality simulation and low flow anaesthesia. Annual Meeting. Association for Low Flow Anaesthesia (ALFA), Bristol Medical Simulation Centre, Bristol, England, July 14, 2005

Nuclear Magnetic Resonance Simulation, University of Florida Institute of Food and Agricultural Sciences (IFAS) College of Agricultural and Life Sciences (CALS) "Creating Virtual Labs" Workshop, Digital Worlds Institute, Norman Hall Gym, University of Florida campus, Gainesville, Florida, August 16, 2005

Free Educational Simulation of the Anesthesia Machine Pre-Use Check, Chinese Society of Anesthesiologists annual meeting, Guangzhou, China, September 4, 2005

Lampotang S, Moon S, Carr RM, Lizdas DE, Feldman JM, Zhang RS: Anesthesia machine preuse check survey - Preliminary results. Poster presentation at the Annual Meeting of the American Society of Anesthesiologists, Atlanta, Georgia, October 24, 2005

Anesthesia machine function. Lecture. Pritzker Auditorium, Feinberg Pavilion, Northwestern Memorial Hospital, Chicago, IL, November 6, 2005

Pre-Use Machine Inspection Workshop. Anesthesiology Department Workshops & Seminars. Anesthesia Machine Workshop: Understanding Our Work "Spouse". Northwestern University, Chicago, Illinois, November 6, 2005

Food & Drug Administration Office of Device Evaluation Vendor Day, Rockville, Maryland, November 16, 2005

3rd Partnership in Global Learning conference: "Consolidating eLearning Experiences", Applying learning object principles to simulation. São Paulo, Brazil, December 1, 2005

American Society of Anesthesiologists Simulation Saturday. Simulation at the University of Florida. University of Florida, Gainesville, Florida, March 11, 2006

Enhancing teamwork with technology; **and** Demonstration of HPS and VAM. NETC 2006. National Extension Technology, Advanced Learning and Technology, Gainesville, Florida, May 9, 2006

Hands-on workshop using the Human Patient Simulator, Japanese Society of Anesthesiologists 53rd Annual Meeting, "New Territory in Anesthesiology", Kobe, Japan, June 1, 2006

A simulation-based e-learning system for the anesthesia machine pre-use check, Japanese Society of Anesthesiologists 53rd Annual Meeting, "New Territory in Anesthesiology", Kobe, Japan June 3, 2006

Simulateurs corps entiers, (Full-scale mannequin patient simulators). Visiting Professor; *lecture delivered in French*. Hôpitaux Universitaires de Genève, Journée Risques et sécurité en médecine: La simulation: du concept à l'utilisation: (Risk and Safety in Medicine Day: Simulation: From concept to deployment). Thème: "Le rôle de la simulation dans la

gestion et la prévention des risques en médecine". (Theme: The role of simulation in the management and prevention of hazards in medicine). Geneva, Switzerland, June 16, 2006

Sécurité des appareils d'anesthésie: vérification avant utilisation et sa simulation, (Safety of anesthesia equipment: Simulation of the pre-use check). Visiting Professor; *lecture delivered in French*. Hôpitaux Universitaires de Genève, SERVICE D'ANESTHESIOLOGIE ENSEIGNEMENT. COURS POST-GRADUES, (Postgraduate courses in anesthesia instruction) Geneva, Switzerland, June 19, 2006

Regulating Oxygen Concentration. Lecture at American Society of Anesthesiologists Annual Meeting Panel "Only You Can Prevent... OR Fires", Chicago, IL, October 15, 2006

Training Anesthesia Personnel to Keep Pace with New Technology. Lecture at American Society of Anesthesiologists Annual Meeting Panel "Hazards of the Modern Anesthesia Workstation - Prevention, Diagnosis, and Treatment", Chicago, IL, October 16, 2006

University of Florida - 2006 Faculty Showcase & Symposium, Grand Ballroom, Reitz Union building University of Florida campus, Gainesville, Florida, November 7, 2006

Mannequins, simulators and e-learning in medicine. Medical Update Lecture Series. University of Mauritius, Le Réduit, Mauritius, July 25, 2007

Keeping cool under (heat) stress. Invited Speaker. Gainesville Rotary Club, Gainesville, Florida, September 4, 2007

Anesthesia machine malfunction (lecture) **and** Anesthesia machine pre-use check (workshop) (September 8). Knowing Our Work Spouse. Northwestern Memorial Hospital Anesthesia Machine Workshop, Chicago, Illinois, September 8, 2007

Keeping cool under (heat) stress. Invited Speaker. National Football League Headquarters, New York, New York, November 13, 2007

The virtual patient: biosimulation in anaesthesia. Invited Speaker. EUFEPS Conference on Optimising Drug Discovery and Development: Integrating Systems Approaches into Pharmaceutical Sciences. Basel, Switzerland, December 5, 2007

Tools for understanding the anesthesia machine. Visiting Professor. Hospital for Special Surgery, New York, New York, April 17, 2008

A panoramic display-based simulation with interactive, dynamic background; Step-by-step-building of a microsimulator (flatscreen simulator); and Simulated anesthesia experience simulation. International Meeting on Simulation in Healthcare. San Diego, California, September 14-15, 2008

The physicality-virtuality continuum in simulation and education in anesthesia (Acceptance lecture as recipient of the SEA/Duke award) **and** A tale of two simulators. Annual Meeting. Society for Education in Anesthesia, San Francisco, California, October 12, 2007

University of Florida Center for Simulation, Advanced Learning and Technology; The ASA Simulation Network: information for prospective centers (workshop panelist); **and** Transparent reality simulation enhances learning of anesthesia machine function and dynamics (October 14); **and** Anesthesia machines of 2007—how to make them work for you (lecture and workshop) (October 15). Annual Meeting. American Society of Anesthesiologists, San Francisco, California, October 13-15, 2007

A panoramic display-based simulation with interactive, dynamic background; Step-by-step-building of a microsimulator (flatscreen simulator). International Meeting on Simulation in Healthcare. San Diego, California, January 14-15, 2008

Simulated anesthesia experience simulation. International Meeting on Simulation in Healthcare. San Diego, California, January 14-15, 2008

University of Florida College of Dentistry, Lunch -n- Learn: "Simulation Education at UF HSC and Avenues for Collaboration". UF Dental School, Jan. 28, 2008

University of Florida Health Science Center Instructional Support Committee. "Update on Simulation Technology & Education at the UF Health Science Center", February 20, 2008

Understanding modern anaesthetic machines; VAM and WFSA; **and** Inhalation induction with a panoramic, screen-based simulation. World Congress of Anaesthesiologists. Cape Town, South Africa, March 4-7, 2008

Simulation Faculty Learning Community Inaugural Lecture: "Screen-Based, Web-Enabled and Panoramic Simulations", Health Professions, Nursing and Pharmacy (HPNP) Building, University of Florida Health Science Center, Gainesville, Florida, April 28, 2008

Equipment simulation for education, grand rounds; Screen-based, web-enabled and panoramic simulations, clinical rounds **and** Teach the teacher - how to teach with the simulations on the VAM web site, lecture; **and** A Tour of the Virtual Anesthesia Machine Web Site, lecture. Visiting Professor. Brigham & Women's Hospital, Boston, MA, June 4, 2008

Virtual simulation. Annual Meeting. Society for Education in Anesthesia, Miami, Florida, June 6, 2008

Web-enabled, panoramic and augmented reality simulations, Department of Anesthesia, St. Michael's Hospital, Toronto and Allen Waters' Family Simulation Centre, Visiting Professor Dinner Rounds, Toronto, Canada, July 22, 2008

Cheque previo de la Máquina de Anestesia (The anesthesia machine pre-use check), 37th Congreso Argentino de Anestesiologia, Buenos Aires, Argentina, August 14, 2008

Localización y solución de problemas en la Maquina de anestesia (Troubleshooting the anesthesia machine) – 37th Congreso Argentino de Anestesiologia, Buenos Aires, Argentina, August 14, 2008

Simulación en la VAM (Simulations at the Virtual Anesthesia Machine web site) – 37th Congreso Argentino de Anestesiologia, Buenos Aires, Argentina, August 14, 2008

Quarles J, Lampotang S, Fischler I, Fishwick P, Lok B: A Mixed Reality System to Enable Collocated After Action Review. Presented at the International Symposium on Mixed and Augmented Reality (ISMAR), Cambridge, United Kingdom, September 2008 (Presented by John Quarles)

The Physicality-Virtuality Continuum of Anesthesia Simulation at UF, University of Florida Department of Anesthesiology Golden Anniversary Celebration, Gainesville, Florida, October 16, 2008

Advanced Workshop on the Aestiva and Apollo Anesthesia Machines (sessions I **and** II). Annual Meeting. American Society of Anesthesiologists, Orlando, Florida, October 17-20, 2008

Emerging Technologies and the Future of Educational Simulations – Keynote address. What Really Works in Educational Simulations for Healthcare Conference organized by the Health Education Technology Research Unit (HETRU) at the University of Ontario Institute of Technology (UOIT) and the Network of Excellence in Simulation for Clinical Teaching & Learning (NESCTL), Oshawa, Ontario, Canada, Nov 22, 2008

Writing a winning Simulation Application (Novice). Post Graduate Course International Meeting on Simulation in Healthcare, Lake Buena Vista, Florida, January 11, 2009

Roundtable State-of-the-Art: Serious Games & Virtual Environments in Healthcare, International Meeting on Simulation in Healthcare, Lake Buena Vista, Florida, January 12, 2009

American Association of Nurse Anesthetists (AANA) Faculty Development Workshop, Renaissance Orlando Resort at SeaWorld, Orlando, Florida, February 25, 2009

Dinner lecture, Simulation in Anesthesia, DC Society of Anesthesiologists, Washington, DC, April 7, 2009

NYU Medical Center. Visiting Professor. Anesthesiology Departmental <u>Grand Rounds</u>, "Transparent and Augmented Reality Simulations in Anesthesia", New York City, NY, August 19, 2009

Hands-on station for the Augmented Apollo Workstation. Northwestern University, Anesthesiology Department Workshops & Seminars. Anesthesia Machine Workshop: *Understanding Our Work "Spouse*". Feinberg School of Medicine, Northwestern Memorial Hospital, Chicago, IL, September 12, 2009

Research: What Has the University of Florida Done for You Today? at the invitation of Dr. Robert and Mrs. Rosita Williams, Vicar's Landing, Ponte Vedra Beach, Florida, September 30, 2009

Fundamentals of Modern Anesthesia Machines. Workshop. Annual Meeting, American Society of Anesthesiologists, New Orleans, Louisiana, Morial Convention Center, New Orleans, LA, October 20, 2009

UF HSC Symposium for Teaching and Learning with Technology, Development and Applications of UF Technology for Simulation in Healthcare in the Last Quarter Century, Communicore Building, University of Florida, Gainesville, Florida, March 8, 2010

The UF Patient Simulation Triangle: Merging Physical, Virtual and Human Simulations - A Personal Interactive Experience, Oak Hammock, Gainesville, Florida, May 6, 2010

Simulation - A fertile and growing research field for patient safety and promotion and tenure. Anesthesiology Research Rounds, Nanoscale Research Facility, University of Florida, Gainesville, FL, June 2, 2010

University of Toronto, Wilson Centre. Research Opportunities in Simulation, Toronto, ON, Canada, September 30, 2010

Simulation in Anesthesia at the University of Florida: University of Toronto, Toronto General Hospital, Department of Anesthesia, Perioperative Interactive Education (PIE) group, September 30, 2010

Anesthesia Machine Workshop. Annual Meeting, American Society of Anesthesiologists, San Diego Convention Center, San Diego, CA, October 18, 2010.

Lampotang S, Akrawi W, Egan R, Ehrenwerth J, Eisenkraft J, Feldman JM, Loeb B, Philip J, Schoenhage K, Whittler S: Anesthesia Machine Workshop. Annual Meeting, American Society of Anesthesiologists, McCormick Place, Chicago, IL, October 17, 2011

Throwing patient safety for a loop. University of Florida Anesthesiology Department Research Lecture Series, Gainesville, FL, November 16, 2011

Subclavian central venous access simulator, Serious Games Arcade, International Meeting on Simulation in Healthcare, San Diego, CA, January 30, 31, 2012

Profiled vessel model for simulating bladder cystometrogram for urine drainage management, International Meeting on Simulation in Healthcare, San Diego, CA, January 31, 2012

Troubleshooting hypoxic oxygen supply conditions. Northwestern University, Anesthesiology Department Workshops & Seminars. Anesthesia Machine Workshop: *Understanding Our Work "Spouse*". Feinberg School of Medicine, Northwestern Memorial Hospital, Chicago, IL, February 4, 2012

Air-cooled football pads and urine drainage. Ocala Rotary Club, Ocala, FL, April 30, 2012 Importance of simulation in improving clinical outcomes. TeleFlex Medical, Reading, PA, July 12, 2012

Adult Learning in Healthcare: Utilizing Advanced Techniques for Improved Patient Outcomes. Lecture at Train the Trainer Course: Ultrasound-Guided Central Venous and Arterial Access: Compliance with Practice, Marriott at the Texas Medical Center, Houston, TX. August 24, 2012

Samsun Lampotang, Faisal Masud, Jessica Wallace: Faculty at the "Procedural Complications: Recognition and Management" Simulation Station at Train the Trainer Workshop: Ultrasound-Guided Central Venous and Arterial Access: Compliance with Practice, (Workshop) Methodist Institute for Technology, Innovation & Education (MITIE), Methodist Hospital, Houston, TX, August 25, 2012

Lampotang S, Akrawi W, Ehrenwerth J, Eisenkraft J, Feldman JM, Philip J, Schoenhage K, Whittler S: Anesthesia Machine Workshop. Annual Meeting, American Society of Anesthesiologists, Washington DC, October 15, 2012

Keynote lecture: Emerging I2 (Innovation and Integration) Trends in Simulation Technology, Simulation Summit, Ottawa Convention Centre, Ottawa, Canada, November 17, 2012

Best Emerging Concepts and Innovative Technologies paper presentation: A Subset of Mixed Simulations: Augmented Physical Simulations with Virtual Underlays. Lecture, Interservice/Industry Training Simulation and Education Conference (I/ITSEC), Orlando, FL, December 5, 2012

Simulation as Clinical and Translational Science. University of Florida Clinical and Translational Science Institute Seminar series, Gainesville, FL, January 9, 2013

An iPad simulation of skin prepping, Lecture at the University of Florida Biomedical Engineering Department Simulation Workshop, Gainesville, FL, January 24, 2013

Lizdas DE, Gravenstein N, Luria I, Lampotang S: An iPad simulation of skin prepping. (Oral presentation by Lampotang); International Meeting on Simulation in Healthcare, Orlando, FL, January 29, 2013

Lampotang S, Lizdas DE, Bisht Y, Luria I, Gravenstein N: An interactive iPad simulation of torso ultrasonography. (Oral presentation by Lampotang); International Meeting on Simulation in Healthcare, Orlando, FL, January 29, 2013

Simulation in Healthcare and Patient Safety: Lecture to Retired Faculty of University of Florida at Harn Museum, Gainesville, FL, March 13, 2013

Mixed Simulators: Augmented Physical Simulators with Virtual Underlays. IEEE Virtual Reality 2013, Orlando, FL, March 18, 2013

Virtual Humans in Simulated Clinical Settings, SESAM 2013 lecture, Porte de la Villette, Paris, France, June 13, 2013

Personalized Medicine: The Future is Now. Medical Update lecture series. Apollo Bramwell Hospital, Moka, Mauritius, July 11, 2013

Ehrenwerth J, Lampotang S, Akrawi W, Eisenkraft J, Feldman JM, Philip J, Schoenhage K, Whittler S: Anesthesia Machine Workshop. Annual Meeting, American Society of Anesthesiologists, San Francisco, CA, October 14, 2013

Pervasive Simulation, Gaming and Mixed Reality: Lecture at Using Emerging Technology in Simulation Curricula Pre-Conference; Asia Pacific Meeting on Simulation in Healthcare, Shanghai, China, October 24, 2013

Problems in conducting simulation-based research. Panelist: Asia Pacific Meeting on Simulation in Healthcare, Shanghai, China, October 26, 2013

Patient-Centered Simulation: Race-specific propofol pharmacodynamics modeling for procedural sedation. Asia Pacific Meeting on Simulation in Healthcare, Shanghai, China, October 27, 2013

Impact and Prevalence of Dependent Loops in Urine Drainage Tubing, e-lecture at Electronic Urine Output Monitoring (eUOM), January 8, 2014 morning session of Smart Monitoring 2014: Pathways to Automated Critical Care, <a href="http://smartmonitoring.org/program\_2014.cfm">http://smartmonitoring.org/program\_2014.cfm</a>, San Francisco, CA, January 8, 2014

The Circle of Innovation. Invited speaker. Society for Technology in Anesthesia/Foundation for Anesthesia Education and Research, Orlando, FL, January 18, 2014

Lecture to UF MD/PhD program: Patient-Centered Medicine: Race-specific propofol pharmacodynamics modeling for procedural sedation. January 22, 2014

Patient-Centered Simulation: Race-specific propofol pharmacodynamics modeling for procedural sedation. Lecture, International Meeting on Simulation in Healthcare, San Francisco, CA, January 27, 2014

The physicality-virtuality continuum in simulation in healthcare. Lecture, Stanford University, January 30, 2014

Simulation in healthcare. Lecture to UF Academic and Professional Assembly (APA), Gainesville, FL, February 11, 2014

Patient-Centered Anesthesia: Race-Specific Propofol Pharmacodynamics during Procedural Sedation. Grand Rounds Lecture, Northwestern University, Chicago, IL, February 14, 2014

Troubleshooting hypoxic oxygen supply conditions. Northwestern University, Anesthesiology Department Workshops & Seminars. Anesthesia Machine Workshop: *Understanding Our Work "Spouse*". Feinberg School of Medicine, Northwestern Memorial Hospital, Chicago, IL, February 15, 2014

A New UF CTSI Core: Simulation in Healthcare. Presentation at UF CTSI Service Operation Directors meeting, CTRB Building, Gainesville, FL, June 26, 2014

Preventing and Managing Surgical Fires, 43<sup>rd</sup> CRNA Refresher Courses, Orlando, FL, November 14, 2014

Translational Simulation in Healthcare, 43<sup>rd</sup> CRNA Refresher Courses, Orlando, FL, November 14, 2014

Troubleshooting and Managing Anesthesia Machine Failures, 43<sup>rd</sup> CRNA Refresher Courses, Orlando, FL, November 14, 2014

Presentation to CTSI Design Studio of pulse oximeter patient empowering feature "Clinical evaluation of a pulse oximetry-based patient empowerment system to reduce hypoventilation and audible alarms," including Citizen-Scientist Alan Porcher, November 19, 2014

Basics of Ultrasound in Regional Anesthesia. Lecture, World Congress of Regional Anesthesia and Pain Therapy, Cape Town, South Africa, November 25, 2014

Basics of Ultrasound in Regional Anesthesia. Workshop using UF regional anesthesia mixed simulator, World Congress of Regional Anesthesia and Pain Therapy, Tygerberg campus, Stellenbosch University, Cape Town, South Africa, November 25, 2014

A Mixed Reality Simulator of Thoracic Regional Anesthesia. Lecture. World Congress of Regional Anesthesia and Pain Therapy, Cape Town, South Africa, November 26, 2014

Clinical Team Training with Virtual Humans at UFHealth. UF Health Surgical Safety Initiative Mandatory Meeting (all operating rooms stay closed and start late that morning; all surgical personnel have to attend this one hour presentation on surgical safety). Presented positive results on actual clinicians speaking up in a simulated environment as a result of Virtual Human–enabled team training in speaking up and using the AHRQ TeamSTEPPS CUS protocol, UF Medical Campus, Gainesville, Florida, January 30, 2015

Faculty Ultrasound/Epidural Workshop, Davison/Lowenstein Conference Room, Massachusetts General Hospital, Boston, February  $4^{th}$ , 5-7 pm, (*Presented by David Edwards, MD*; the UF Thoracic Regional Anesthesia Simulator was used as one of the stations at the workshop).

3<sup>rd</sup> Annual Acute Pain Medicine & Regional Anesthesia Conference, (for military and civilian anesthesiologists interested in trauma and perioperative pain management), February 13-15, 2015, Baltimore, Maryland. (*The UF Thoracic Regional Anesthesia Simulator was presented by Patrick Tighe, MD*)

In Progress Review for DoD grant W81XWH-14-1-0113 to USAMRAA, JPC1, TATRC at Ft. Detrick, MD on 8/11/15

Lampotang S: Normal operation of anaesthesia machine, Association of Anaesthesiologists of Mauritius XXIII Annual Scientific Conference, Le Méridien Hotel and Resorts, Pointe aux Piments, Mauritius, August 29-30, 2015

Lampotang S: Preoperative check of anaesthesia machine, Association of Anaesthesiologists of Mauritius XXIII Annual Scientific Conference, Le Méridien Hotel and Resorts, Pointe aux Piments, Mauritius, August 29-30, 2015

Lampotang S: Surgical fire prevention and management, Association of Anaesthesiologists of Mauritius XXIII Annual Scientific Conference, Le Méridien Hotel and Resorts, Pointe aux Piments, Mauritius, August 29-30, 2015

Understanding and Managing Urine and Chest Drainage Systems, Medical Update lecture, University of Mauritius, Le Réduit, Mauritius on September 2, 2015

Lampotang S: The Zen of Next-Gen Simulator Design, Workshop, Medicine X Ed, Stanford, CA on 9/24/15

Lampotang S, Philip J, Loeb R, Ehrenwerth J, Eisenkraft J, Feldman JM, Schoenhage K: Anesthesia Machine Workshop. Annual Meeting, American Society of Anesthesiologists, San Diego, CA, October 25, 2015

Andrew Robb, Andrew Cordar, Samsun Lampotang, Casey White, Adam Wendling, Benjamin Lok: Teaming Up With Virtual Humans: How Other People Change Our Perceptions of, and Behavior with, Virtual Teammates. Selected as best papers published in IEEE TVCG in VR and AR for presentation at a special session on VR/AR at SIGGRAPH ASIA, November 5, 2015 in Kobe, Japan (*presented by Andrew Robb, PhD*)

# DEMONSTRATIONS OF SIMULATION AND TRAINING EQUIPMENT

Samsun Lampotang, Ph.D.

American Society of Anesthesiologists. Annual Meeting. Atlanta, Georgia, October 11-13, 1987

Ninth World Congress of Anesthesiologists, Washington, DC, May 23-24, 1988

Congress of German Society of Anesthesiologists, Mannheim, Germany, September 22-24, 1988

American Society of Anesthesiologists. Annual Meeting. San Francisco, California, October 10-12, 1988

American Society of Anesthesiologists. Annual Meeting. New Orleans, Louisiana, October 16-18, 1989

12th Annual Parent-Spouse Day. University of Florida College of Medicine, Gainesville, Florida, February 2, 1990

Visiting Professor, Dr. Elena A. Damir, University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, October 30, 1990

"Florida's Future Showcase." Governor Chiles' Inauguration, Tallahassee, Florida, January 7-8, 1991

Anesthesia Patient Safety Foundation. Executive Committee Meeting, Department of Anesthesiology, Gainesville, Florida, May 9, 1991

Harvard Medical Center Visitors. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, July 30, 1991

Demonstration for Anesthesia Patient Safety Foundation Video. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, July 31, 1991

Visitors from Ohmeda. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, August 26, 1991

Visitors from Canada Aerospace Electronics-Link. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, August 29, 1991

Communicore demonstration. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, August 30, 1991

Hewlett Packard Boeblingen Consultant, Mr. Tom Clemens. University of Florida College of

Medicine, Department of Anesthesiology, Gainesville, Florida, October 21, 1991 Departmental Visitors: Dr. Margaret Beutler, Germany; Dr. D.A. Rocke, South Africa; and Dr. Pierre Clydman, The Netherlands. University of Florida College of Medicine, Department of Anesthesiology, October 23, 1991

Ohmeda Visitor, Robert Tham, Ph.D. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, November 4, 1991

Demonstration of training devices and a videotape of the simulator. Bielefeld Anaesthesiologisches Colloquim. Konzepte zur Risikominderung in der Anaesthesiologie, Bielefeld, Germany, November 15-16, 1991

Preventing risk and solving problems in anesthesia using hands-on simulation. Continuing Medical Education Course. Department of Anesthesiology, University of Florida College of Medicine, Anesthesia Patient Safety Foundation, and Anesthesiology Alumni Association of Florida, Inc., Gainesville, Florida, November 30-December 1, 1991

Department Visitors: Darrell McCormick, Derek Alden, July 8, 1992; Steve Jackson, Joe Andiriani, July 24, 1992

Preventing risk and solving problems in anesthesia using hands-on simulation. Continuing Medical Education Course. Department of Anesthesiology, University of Florida College of Medicine, Anesthesia Patient Safety Foundation, and Anesthesiology Alumni Association of Florida, Inc., Gainesville, Florida, August 20-21, 1992

Simulator hands-on sessions. Third Annual Florida Society of Technicians and Technologists. September 26-27, 1992

Gainesville Anesthesia Course for Sales Representatives (GACSR #4): October 26-28, 1992

Simulator demonstration on machine faults. Gainesville Anesthesia Course for Engineers and Marketing Personnel. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, March 17, 1994

Demonstration of the anesthesia simulator. Guest Lecturer. Florida Society of Anesthesia Technicians, Gainesville, Florida, September 24-25, 1994

Demonstration of the Loral Human Patient Simulator. Loral Data Systems Booth. Annual Meeting of the American Society of Anesthesiologists, San Francisco, California, October 15-19, 1994

Human Patient Simulator Ribbon Cutting Ceremony. Lively Technical Center. Tallahassee, Community College, Tallahassee, Florida, April 7, 1995

Demonstration of the Loral Human Patient Simulator. Ribbon Cutting Ceremony. University of Florida College of Engineering, Gainesville, Florida, May 8, 1995. (In attendance were: Dr.

Sandra A. Glass of the Keck Foundation, Dr. Karen Holbrook and Paul Robell.) Demonstration of the Loral Human Patient Simulator. Visiting Professors Drs. Iwase and Hanzawa from Dokkyo University, Japan. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, June 28, 1995

Technical review and demonstration of the GRADS and LCS research projects. Hewlett Packard, Ohmeda, and University of Florida Meeting. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, September 21, 1995

Demonstration of the Loral Human Patient Simulator. Executives from Science Applications International Corporation. University of Florida College of Medicine, Department of Anesthesiology, Gainesville, Florida, October 5, 1995

Demonstration of the Loral Human Patient Simulator. William Lacourciere, Novametrix Chief Executive Officer and Philip Nuzzo, Novametrix Director of Marketing, Gainesville, Florida, April 9, 1996

Demonstration of the Loral Human Patient Simulator. Mike Murphy, MD, FRCP, Commissioner of Emergency Health Services, Nova Scotia, Canada, April 10, 1996

Demonstration of the Loral Human Patient Simulator and the Medical Semiautomated Forces to military medical personnel at Ft. Sam Houston, San Antonio, Texas, May 1, 1996. (Supported by Science Applications International Corporation, University of Florida, and Medical Education Technologies, Inc.)

Demonstration of the Loral Human Patient Simulator. University of Florida College of Nursing (Dr. Joyce Stechmiller and General Marianne Chapman), Gainesville, Florida, July 1, 1996

Demonstration of the Loral Human Patient Simulator to Dr. Ronald Kudla, Director of the Office of Technology Licensing of the University of Florida, Gainesville, Florida, July 24, 1996

Demonstration of the Loral Human Patient Simulator to Mr. William Needle, Esq., Patent Counsel to the University of Florida and partner in the Atlanta Law Firm, Needle & Rosenberg, University of Florida, Gainesville, Florida, July 25, 1996.

Demonstration of the Loral Human Patient Simulator to Mr. Fred M. Hunter, Vice President of Sales, Gibeck, Inc., University of Florida, Gainesville, Florida, September 17, 1996

Demonstration of the Loral Human Patient Simulator to Kim Davis and Susan DiMarino, Johnson & Johnson Medical Instrumentation Engineers, Gainesville, Florida, October 16, 1996

Demonstration of the Loral Human Patient Simulator to Major Paul P. Barry, Project Director, Distributed Interactive Simulation, U.S. Army Simulation, Training and Instrumentation Command (STRICOM), Orlando, Florida, December 12, 1996

The research applications of the Human Patient Simulator. Dr. Hussein Dashti, Vice-Dean,

Administration and Finance; Mr. Abdullatif Ahmad Al-Bader, Dean, Faculty of Medicine; and Dr. Habib Abdul, Associate Professor, Department of Pharmacology, Kuwait University, Kuwait, January 25, 1997

Demonstration of the Human Patient Simulator to Bengt Hermanrud, Ph.D., Vice President for Marketing, Siemens Medical Systems, Inc, Danvers, Massachusetts, January 30, 1997

Demonstration of the Human Patient Simulator to Vic Dragon, Unitron Medical Communications, Clearwater, Florida, January 30, 1997

Demonstration of the Human Patient Simulator to Cindy Mott, Shands Home Care Nursing, Gainesville, Florida, March 19, 1997

Demonstration of the Human Patient Simulator for the Mini Medical School, Gainesville, Florida, March 19, 1997

Demonstration of the Human Patient Simulator to: Shan Padda, Chief Executive Officer, Stephen L. Holden, Senior Vice President and Chief Financial Officer, and Clint Deckert, Principal Electronics Engineer, Sabratek, Gainesville, Florida, April 24, 1997

Demonstration of the Human Patient Simulator to: Tuan Bui, PhD, MBA, Vice President for Research and Development, Sabratek, Niles, Illinois, August 14, 1997

Demonstration and presentation of simulator-based usability studies to Dr. Michael Marks, Senior Lecturer, Department of Pediatrics, University of Melbourne, Australia, Gainesville, September 10, 1997

Demonstration of the Human Patient Simulator to: Alexander Gelbman, Business Director, Becton Dickinson (Franklin Lakes, New Jersey), Gainesville, Florida, October 30, 1997

Demonstration of the Human Patient Simulator to: Prof. Dr. med. Hugo van Aken, Director of the Klinik und Poliklinik fur Anasthesiologie und operative Intensivmedizin der Westfalischen Wilhemls-Universitat Munster, of the University of Munster, Germany, Gainesville, Florida, November 20, 1997

Demonstration of the Human Patient Simulator to: Gregory L. Merril, President and CEO of HT Medical, Rockville, Maryland; Richard L. Stacey, Vice President of Marketing, HT Medical; and Richard L. Cunningham, Director of Engineering, HT Medical. Gainesville, Florida, December 16, 1997

Demonstration of the Human Patient Simulator to: Charles Shadd, Esq. of Saalfield, Coulson, Shadd & Jay, PA (defense attorneys in a clinical malpractice suit). November 10, 1997

Demonstration of the Human Patient Simulator. 20th Annual Family and Friends Day. University of Florida College of Medicine, Gainesville, Florida, February 14, 1998

Demonstration of the Human Patient Simulator to: Jim Brinsfield, Engineer, Marquette Medical Systems, Milwaukee, Wisconsin; Mathew R. Cavanaugh, Director of New Product Development/Pulmonary Care, Hill-Rom, Charleston, South Carolina; Herb F. DeRiesthal, Project Manager, Pfizer, New York, New York; David Lovejoy, Advanced Development Manager, Marquette Medical Systems, Milwaukee, Wisconsin; Philip Weinfurt, Manager, New Technology Development/Monitoring Products, Marquette Medical Systems, Milwaukee, Wisconsin; Barry Hand, Senior Project Engineer/Pulmonary Business Unit, Hill-Rom, Charleston, South Carolina, Gainesville, Florida, March 18, 1998

Demonstration of the Human Patient Simulator. Mini Medical School. University of Florida College of Medicine, Gainesville, Florida, April 4, 1998

Programmatic report on the Human Patient Simulator. Faculty Advisory Board Meeting. University of Florida Brain Institute, University of Florida, Gainesville, Florida, April 9, 1998

Demonstration of the Human Patient Simulator to: G. Ram Bhat, PhD, Corporate Director, Corporate Office of Science and Technology, Johnson and Johnson, New Brunswick, New Jersey, Gainesville, Florida, April 21, 1998

Demonstration of the Human Patient Simulator to: Mary B. Carter, MD, PhD, Visiting Professor from the Department of Surgery, University of Louisville, Louisville, Kentucky, Gainesville, Florida, May 5, 1998

Demonstration of the Human Patient Simulator to: Kenneth J. Giacin, General Manager, Professional Exploratory Products, Johnson and Johnson, New Brunswick, New Jersey **and** Ravi C. Gupta, Specialist in Health Care Business Development and Commercializing New Technologies, Gillette, New Jersey, Gainesville, Florida, May 15, 1998

Demonstration of the Human Patient Simulator to: Dr. Toshiaki Shiomi, Associate Professor of Cardiology, Aichi Medical University, Japan and Dr. T. Ito, Associate Professor of Public Health, Aichi Medical University, Japan, November 10, 1998

Demonstration of the Human Patient Simulator and the HT Medical Pre-Op Bronchoscopy System. University of Florida Brain Institute, Celebrating Dr. Rhoton, Gainesville, Florida, January 9, 1999

Demonstration of the Human Patient Simulator. Kathryn Lombardi and guests. University of Florida, Gainesville, Florida, January 15, 1999

Demonstration of the Human Patient Simulator. Annual University of Florida Foundation Board of Overseers Retreat, University of Florida Brain Institute, February 27, 1999

Demonstration of the Human Patient Simulator to Mr. Gillert, Public Affairs Division of the Office of the Assistant Secretary of Defense, American Forces Information Services, Gainesville, Florida, March 22, 1999

Multidisciplinary simulation computer lab **and** the Human patient simulator (April 3). Visiting Department Chairmen from the University of Illinois College of Medicine, Gainesville, Florida, April 2-3, 1999

Demonstration of the Human Patient Simulator to Dr. John H. Linehan, Vice President, Biomedical Engineering Programs, The Whitaker Foundation, Rosslyn, Virginia. Gainesville, Florida, April 113, 1999

Demonstration of the Human Patient Simulator at the University of Florida Brain Institute Alumni Association's Back to College Weekend. Gainesville, Florida, April 17, 1999

Demonstration of the Human Patient Simulator. United States Congress, for the Department of Defense, Washington, DC, May 13, 1999

Demonstration of the Human Patient Simulator to: Jos J. Settels, BioMedical Instrumentation, TNO Institute of Applied Physics, Amsterdam, Netherlands and Jolene S. Shorr, Senior Clinical Research Scientist, Alliance Pharmaceutical Corporation, San Diego, California, Gainesville, Florida, May 28, 1999

Demonstration of the Human Patient Simulator: Program for Early Engineering Knowledge (PEEK). University of Florida, Gainesville, Florida, June 9, 1999

Demonstration of the Human Patient Simulator to: Yoshinobu Higashi, Manager, International Pharmaceutical Affairs, Hisamitsu Pharmaceutical Company, Inc.; Masaki Sato, Assistant Manager, International Clinical Development, Research and Development Tokyo Tanabe Company, Ltd; Katsuhiro Nakamura, Manager, International Research and Development Planning Section, Hisamitsu Pharmaceutical Company, Inc; Midori Ogassaware, Manager, Global Pharmaceutical Development, Toray Industries, Inc; Suzuki Yoichi, Chief Research Chemist, Nissan Chemical Industries, Ltd; Rich W. Friederich, CPA, Vice President and Chief Financial Officer, Beckloff Associates, Inc; and Mario F. Sylvestri, Pharm D, PhD, Executive Director, Clinical Affairs, Beckloff Associates, Inc. University of Florida Brain Institute, Gainesville, Florida, July 6, 1999

Demonstration of the Human Patient Simulator to: Elizabeth R. Bedell, PhD, Director of Major Gifts, University of Florida Health Science Center, Gainesville, Florida, July 14, 1999

Demonstration of the Human Patient Simulator to: Dr. Robert Doughty, Nemours Foundation, Jacksonville, Florida, Gainesville, Florida, July 29, 1999

Demonstration of the Human Patient Simulator to: Mac Stipanovich and Jim Magill, Lobbyists, Gainesville, Florida, August 18, 1999

Demonstration of the Human Patient Simulator to: Mark Rise, PhD, Technical Fellow, Medtronic Neurological, Gainesville, Florida, August 23, 1999

Demonstration of the Human Patient Simulator to: Bill Hittel, Medical Liaison Director; Regina McEwen, Territory Manager; Tom Malik, Hospitals Manager; Paul Kustera, Hospital Territory Manager, Parke-Davis, Inc., University of Florida Brain Institute, September 21, 1999

Demonstration of the Human Patient Simulator to: State of Florida Legislative Aides: Janet Oehmig from Representative Nancy Argenziano, Carol Deinhart from Representative Bob Casey, Crissy Goodwin from Representative Bob Casey, Mike Murtha from Senator Kirkpatrick, Paul Hull from Senator Jim King, Sharon Nehring from Representative George Albright, Patsy Eccles lobbyist for Shands Gainesville/Jax out of Tallahassee, Allison Hunt Larry Overton and Associates, University of Florida Brain Institute, September 21, 1999

Demonstration of the Human Patient Simulator to: Lee Limbird, Associate Vice Chancellor for Research, Beverly Bond, Vice Chancellor for Development, Bob Feldman, Associate Vice Chancellor for Medical Center Development, Vanderbilt University, University of Florida Brain Institute, September 23, 1999

Demonstration of the Preoperative Virtual Reality Simulator: Bronchoscopy at the University of Florida College of Medicine Resident's Fair, University of Florida, October 1, 1999

Demonstration of the Human Patient Simulator at "The Child's Brain Matters Symposium". University of Florida Brain Institute, October 8, 1999

Demonstration of the Human Patient Simulator to: Michael S. Golembieski, Senior Director, Planning & Development, Respiratory, Mallinckrodt, Inc., St. Louis, Missouri, University of Florida Brain Institute, October 13, 1999

Demonstration of the Human Patient Simulator to: Mario Silvestri, Executive Director, Clinical Affairs, Beckloff Associates, Overland Park, Kansas and Toshitada Matsuoka, President, International Monitor Corporation, Tokyo, Japan, University of Florida Brain Institute, November 1, 1999

Demonstration of the Human Patient Simulator to: Alan J. Tager, Regional Director, Florida Institute for Neurologic Rehabilitation, Inc, Wauchula, Florida, University of Florida Brain Institute, November 17, 1999

Demonstration of the Human Patient Simulator to: Senator and Mrs. Walter "Skip" Campbell, Jr of Ft. Lauderdale, Florida, University of Florida Brain Institute, November 19, 1999

Demonstration of the Human Patient Simulator to: Alex Grass and Phil Emmer, University of Florida Brain Institute, November 22, 1999

Demonstration of the Human Patient Simulator to: J. Lee Dockery and Michael L. Dockery. University of Florida Brain Institute, November 24, 1999

Demonstration of the Human Patient Simulator to: Rand Wortman, Chief Executive Officer, and

Claudia Chadwick, Director of Cardiovascular Services, May Medical Center, Panama City, Florida. University of Florida Brain Institute, December 17, 1999

Demonstration of the Human Patient Simulator to: Peter Benson, CEO and Christer Jacobsson, Vice President OEM Applications, Optovent AB, Bromma, Sweden, University of Florida Brain Institute, February 8, 2000

Demonstration of the x-ray synchronization device at General Electric Medical Systems, Waukesha, Wisconsin, August 17, 2000

Demonstration of the Human Patient Simulator to Gregory C. Murphy, PhD, School of Public Health, LaTrobe University, Bundoora, Victoria, Australia, at the University of Florida Brain Institute, August 30, 2000

Demonstration of the Human Patient Simulator to Snead Davis and Ollie Boilleau, at the University of Florida Brain Institute, March 9, 2001

Demonstration of the Human Patient Simulator to Ft King Middle School students, at the University of Florida Brain Institute, March 19, 2001

Demonstration of the Human Patient Simulator and the Cervical Motion Sensor. American Association of Clinical Anatomists (AACA). Postgraduate Course in Clinical Aspects of Skull Base and Vertebral Column Anatomy, McKnight Brain Institute, University of Florida, Gainesville, Florida, June 8, 2002

Demonstration of the Human Patient Simulator to Gregory Eckstein, Product Manager, Network Solutions and six other visitors from Philips Medical Systems. McKnight Brain Institute, University of Florida, Gainesville, Florida, November 13, 2002

Demonstration of Human Patient Simulator to University of South Florida delegation hosted by Dr. Lynn Romrell, McKnight Brain Institute, University of Florida, Gainesville, Florida, January 9, 2003

Demonstration of Virtual Anesthesia Machine to delegates from US and Canada from the Coalition for Physician Enhancement (CPE), visiting the UF CARES program. McKnight Brain Institute, University of Florida, Gainesville, Florida, May 1, 2003

Demonstration of Virtual Anesthesia Machine to Luis Castro, Centro Medico Imbanaco, Cali, Colombia and John Corral, Marketing Manager, Respiratory, Tyco Healthcare. McKnight Brain Institute, University of Florida, Gainesville, Florida, June 23, 2003

Demonstration of Virtual Anesthesia Machine to Martin McKenna, General Manager PeriOp Information Systems, GE Medical Systems. McKnight Brain Institute, University of Florida, Gainesville, Florida, June 24, 2003

Demonstration of Virtual Anesthesia Machine to Mike Bunnell, VP Sales and Marketing,

Respironics and Philip Nuzzo, Respironics. McKnight Brain Institute, University of Florida, Gainesville, Florida, July 24, 2003

Demonstration of Virtual Anesthesia Machine to Board of Directors of University of Florida Division of Continuing Education (DOCE). DOCE offices, August 20, 2003

Demonstration of Virtual Anesthesia Machine to Robert E. Cockram, Square One Business Solutions, Inc., McKnight Brain Institute, University of Florida, Gainesville, Florida, August 27, 2003

Demonstration of Virtual Anesthesia Machine to Elizabeth A. Kress, Executive Director, Flight Attendant Medical Research Institute (FAMRI). UF Health Science Center, August 29, 2003

Demonstration of Virtual Anesthesia Machine to UF Telehealth interest group. Health Professions, Nursing and Pharmacy Building, University of Florida, September 9, 2003

Demonstration of Virtual Anesthesia Machine to Vice Admiral Michael Cowan, Surgeon General of the Navy, McKnight Brain Institute, University of Florida, Gainesville, Florida, September 18, 2003

Demonstration of Virtual Anesthesia Machine to IBM executives: IBM/UF Technology Workshop, University of Florida, October 6, 2003

Demonstration of Virtual Anesthesia Machine to Macromedia Director team, Macromedia Headquarters, San Francisco, California, October 13, 2003

Demonstration of Virtual Anesthesia Machine and other transparent reality simulations to the University of Florida Distance Education Advisory Committee, November 6, 2003

Demonstration of Virtual Anesthesia Machine to Professor Kenneth Taylor, Imperial College School of Medicine, Hammersmith Hospital, London, England, and Bayer executives, McKnight Brain Institute, University of Florida, Gainesville, Florida, November 18, 2003

Demonstration of Virtual Anesthesia Machine to Mickey Singer, CEO Medical Manager, at McKnight Brain Institute, March 25, 2004.

Demonstration of the Human Patient Simulator and Virtual Anesthesia Machine Software to Judy Bricker, Vice President, Northern Trust Bank, Naples, Florida and Mary Beth Vallar, Vice President, Northern Trust Bank, Vero Beach, Florida, Gainesville, Florida, April 15, 2004

Demonstration of the Human Patient Simulator and Virtual Anesthesia Machine to visitors from Chengdu Hospital Department of Anesthesiology, China—Jin Liu MD, PhD, Professor and Chairman, Department of Anesthesiology and Intensive Care Unit; Yunxia Zuo, MD, PhD, Associate Professor and Vice Chairman, Department of Anesthesiology and Intensive Care Unit; Bin Liu, MD, Professor and Director, Department of Anesthesiology; Yan Kang, MD, Associate Professor, Director of Intensive Care Unit; and Yan Liao, RN, Head Nurse of the Intensive Care

Unit, November 3, 2004

Virtual Anesthesia Machine (November 5 [3 sessions of 30 people]). Northern Trust Group. McKnight Brain Institute, Gainesville, Florida, November 5, 2004

Demonstration of HPS and VAM to Dr. Hiroshi Taguchi and Dr. Ryoei Ito, Faculty of Bioresources, Mie University, Tsu City, Mie, Japan at the McKnight Brain Institute, April 20, 2005

Pre-Use Machine Inspection, Hands-on Workshop with the new APSF-funded simulation of the anesthesia machine pre-use check, 12.30 - 3.00 pm, Sunday, November 6, 2005 Northwestern University, Chicago, Anesthesiology Department Workshops & Seminars. <u>Anesthesia Machine</u> Workshop: *Understanding Our Work "Spouse*"

Demonstration of Virtual Anesthesia Machine web site simulation portfolio to Mrs. Emily Maren and Erik Swenson, MD, Thomas H. Maren Foundation, Center for Simulation, Advanced Learning and Technology, Gainesville, October 25, 2006

Demonstration of Human Patient Simulator and Virtual Anesthesia Machine to Philips employees taking part in Society of Critical Care Medicine and Shands Hospital at the University of Florida Mini Internship, April 19, 2007

University of Florida, Board of Trustees reception, Virtual Anesthesia Machine, HUB Building, University of Florida campus, Gainesville, Florida, June 14, 2007

Citrus County Community Foundation, Inverness, Florida: demo of VAM simulations for Wann Van Robinson, November 14, 2007

Frances C. and William P. Smallwood Foundation, demo of VAM simulations to Sally Muller, Gainesville, Florida, November 21, 2007

Mixed Simulator and Panoramic Simulation to METI, January 23, 2008

Mixed Simulator and Panoramic Simulation to GE Healthcare, February 5, 2008

Dr. and Mrs. Robert B. Williams, Demo of VAM simulations to potential donor by request of Doug Medlin, March 24, 2008; *led to a \$250K bequest to CSSALT* 

VAM simulations and SAA to Andre Boezaart's guests (Arrow/Teleflex), March 25, 2008

VAM simulations to Jacob Plotzker, Organon, April 1, 2008

Mixed simulator and Panoramic Simulation to Rob Clark and John Felter, April 15, 2008

Panoramic Simulation to visitors from Cook, May 29, 2008

Greg Murad, MD; Assistant Professor in Neurosurgery, University of Florida

Col (Ret). Mark W. Bowyer, MD, Prof of Surgery, Director of Surgical Simulation, Uniformed Services University, 11/2/2011

Neal E. Seymour, MD, Surgery Visiting Professor, Baystate Medical Center, Director, Baystate Simulation Center 11/2/2011

William Lewandowski, Simbionix, 11/7, 2011

David Massias, Shadow Learning; 11/16/2011

Miguel Machado, MD, President of Florida Medical Association 11/18/2011

Wayne Truong, MD at request of Pediatric Surgery chair 12/16/2011

Steven Shafer, MD, Editor of Anesthesia & Analgesia, Visiting Professor, 1/22/2012

Randy Harmatz, Chief Quality Officer, UF & Shands Academic Health Center, 2/16/2012

Anders Ericsson, Florida State University, Visiting Professor, 2/21/2012

Fred Southwick, MD, 3/1/12

Darlene Hicks, American Board of Anesthesiologists 3/2/12

Chris Carnes, Covidien, May 25, 2012

Ben Sosna, Medical Science Liaison at Cadence Pharmaceuticals, May 30, 2012

Greg Leh, TeleFlex Medical, June 1, 2012

Demo of simulations to Vivek Sharma, Piramal Critical Care Medicine Director August 17, 2012

Simulation demo for CoM Dean Good for Committee for Fundraising Drive for Harrell Medical Education Building August 28, 2012

Demo of simulators to University of Florida College of Medicine Alumni for Alumni reunion, October 19, 2012

Demo of UF-designed Central Venous Access simulator: Special event: Interservice/Industry Training Simulation and Education Conference (I/ITSEC), Orlando, FL, December 6, 2012 Lampotang S, Lizdas DE, Bisht Y, Luria I, Gravenstein N: An interactive iPad simulation of torso ultrasonography (Technology demonstration by Lampotang); International Meeting on Simulation in Healthcare, Orlando, FL, January 27, 2013

Lizdas DE, Gravenstein N, Luria I, Lampotang S: An iPad simulation of skin prepping

(Technology demonstration by Lampotang); International Meeting on Simulation in Healthcare, Orlando, FL, January 27, 2013

Demo of mixed simulators to Dr. Colin McCartney, Visiting Professor from University of Toronto Sunnybrook, Gainesville, FL, February 4, 2013

Demonstration of mixed simulators at IEEE VR 2013 FLAVRS (Florida Virtual Reality Simulation) exhibition, Orlando, FL, March 18, 2013

Demonstration of Mixed Simulator of Central Venous Access at University of Washington (Bowdle, Burkhardt, Rooke), Seattle, WA, March 28, 2013

Demonstration of mixed simulator of regional anesthesia to Lou Oberndorf, March 13, 2014

Online demonstration of screen-based simulations to American Board of Anesthesiology, March 23, 2014

Demo of latest simulators to visiting professor Richard Galgon from Univ. of Wisconsin, November 3, 2014

Discussion of simulation center and demo of simulation research to UF Anesthesiology Department Chair applicant Vesna Jevtovic-Todorovic, MD on November 19, 2014

Discussion of simulation center and demo of simulation research to UF Anesthesiology Department Chair applicant Roger Johns, MD on December 19, 2014

Demonstration of cross-sectional literacy and ultrasound imaging trainer/simulator to medical student applicants, January 23, 2015

Demonstration of thoracic regional anesthesia and cross-sectional literacy simulators to, and interview of, faculty applicant Dr. Steve Vose, February 5, 2015

Hands-on demonstration of Virtual Human technology and its application to learn and practice the Agency for Healthcare Research and Quality (AHRQ) TeamSTEPPS CUS (Concerned, Uncomfortable, Safety) Speaking Up protocol including the Two-Challenge Rule at the CTSI informational booth at the College of Medicine Celebration of Research, UF Campus, Gainesville, FL, February 9, 2015

Demonstration of screen-based skin prep simulator and mixed reality thoracic regional anesthesia simulator to, and interview of, faculty applicant Dr. Joseph Hughes, February 12, 2015

Demonstration of augmented reality simulators at Reitz Union North Lawn as sole UF College of Medicine representatives at activities for the inauguration of Dr. Kent Fuchs as the new University of Florida President; 12/2/2015 and 12/3/2015

#### **OUTSIDE CONSULTATIONS**

Samsun Lampotang, Ph.D.

Apotheus Laboratories, Ltd. Consultation on engineering and safety issues. Conducted an external engineering review of the SafeCircuit source control technology and presented review to the Food and Drug Administration's Office of Device Evaluation, Rockville, Maryland. May 11-June 25, 1996

Scott Laboratories. Consultation on design of medical equipment. April 1997 - 2001

Drager Medical Inc. Consultation on design of anesthesia machines. January 2000 - 2002

#### SCIENTIFIC & EDUCATIONAL EXHIBITS

Samsun Lampotang, Ph.D.

Good ML, Lampotang S, Gibby GL, Gravenstein JS: Training in anesthesiology: critical events simulation. Annual Meeting. American Society of Anesthesiologists, Atlanta, Georgia, October 10-14, 1987 First Prize for Best Scientific Exhibit

Good ML, Lampotang S, Gibby GL, Gravenstein JS: Critical events simulation for training in anesthesiology. Fifth International Symposium on Computing in Anesthesia and Intensive Care, San Diego, California, May 16-20, 1988

Good ML, Lampotang S, Gibby GL, Gravenstein JS: Training in anesthesiology: critical events simulation. Annual Meeting. 9th World Congress of Anaesthesiologists. Washington DC, May 22-28, 1988

Good ML, Lampotang S, Gibby GL, Gravenstein JS: Training in anesthesiology using simulation. Anesthesia Patient Safety Foundation/Food and Drug Administration Simulator Educator Workshop, Chicago, September 10-11, 1988

Good ML, Lampotang S, Gibby GL, Gravenstein JS: Training in anesthesiology: critical events simulation. Deutscher Anasthesiekongress, Mannheim, Federal Republic of Germany, September 21-25, 1988

Good ML, Hekker JJ, Lampotang S, Gibby GL, Gravenstein JS: Learning about the anesthesia machine through simulation. Annual Meeting. American Society of Anesthesiologists, San Francisco, California, October 8-12, 1988

Good ML, Ritchie RG, Heffels JJ, Miller B, Lampotang S, Atwater RJ, Newell TR, Pate BL, Beneken JEW, Gravenstein JS: A simulation exercise emphasizing inhalation anesthesia. FDA Anesthesia Simulator Curriculum Conference. Rockville, Maryland, September 22-24, 1989

Good ML, Atwater RJ, Lampotang S, Clark PA, Newell TR, Heffels JH, Gravenstein JS: Can simulation teach clinical skills? Annual Meeting. American Society of Anesthesiologists, New Orleans, Louisiana, October 14-18, 1989

Gibby GL, Lampotang S, Hathiram D, Gravenstein N: In-line, microwave fluid warmer with adaptive, non-invasive control. Annual Meeting. American Society of Anesthesiologists, Las Vegas, Nevada, October 19-23, 1990

Carovano RG Jr, Good ML, Gravenstein JS, Lampotang S, Brient SE, Carovano WA, Cooper EG, de Hair P, Hoag LJ, Safa A, van den Brock M, Yachabach TL: Monitoring instrument training devices for medical education. Annual Meeting. American Society of Anesthesiologists, New Orleans, Louisiana, October 19-21, 1992 **First Prize for Best Scientific Exhibit** 

Anesthesia simulators (workshop) (May 12-16). Founding Congress. European Society of Anaesthesiologists, Brussels, Belgium, May 11-16, 1993

Good ML, Lampotang S, van Meurs W: Experience the simulators. Annual Meeting. The Society for Technology in Anesthesia, Orlando, Florida, January 26-29, 1994

Lampotang S: Education sessions on mechanical faults in the circle system (March 6-8). 68th Clinical and Scientific Congress. International Anesthesia Research Society, Orlando, Florida, March 5-9, 1994

Ohrn MAK, van Meurs W, van Oostrom H, Ayyalsamy A, van der Aa J, Gravenstein JS, Gravenstein N, Good ML, Lampotang S: Neuromuscular blockade and Mapleson D/Bain breathing circuits, two new training devices. Annual Meeting. American Society of Anesthesiologists, San Francisco, California, October 15-19, 1994 **Exceptional Merit for Best Scientific Exhibit** 

Gravenstein D, Gravenstein N, Lampotang S, Melker RJ, Sultan A: Blind intubation simplified by an intelligent light-actuated auditory feedback system. Annual Meeting. American Society of Anesthesiologists, San Francisco, California, October 15-19, 1994

Lampotang S, van Oostrom H, Auzins C, SaGomes E, Johnson N, Gravenstein JS: Influence of compliance and resistance on the distribution of ventilation. Annual Meeting. American Society of Anesthesiologists, Atlanta, Georgia, October 21-25, 1995

Gravenstein D, Lampotang S, Melker R, Doviak R, Hall J: Fiberoptic imaging stylet for intubation. Annual Meeting. American Society of Anesthesiologists, San Diego, California, October 18-22, 1997 Anesthesia Patient Safety Foundation (APSF) Ellison C. Pierce Award for Best Scientific Exhibit on Patient Safety

Gravenstein D, Lampotang S, Melker R, Doviak R, Hall J: Fiberoptic imaging stylet for intubation (December 13-15). Postgraduate Assembly in Anesthesiology. New York State Society of Anesthesiologists, New York, New York, December 13-16, 1997

Lampotang S, Gravenstein D, Melker RJ: The University of Florida experience: fiberoptic intubation stylet. 72nd Clinical and Scientific Congress. International Anesthesia Research Society, Orlando, Florida, March 7-11, 1998

Lampotang S, Liem EB, Lizdas D, Gravenstein D: Web-based educational animation of an anesthesia machine. Annual Meeting. American Society of Anesthesiologists, New Orleans, Louisiana, October 13-17, 2001 Outstanding (First Prize) Scientific & Educational Exhibit from American Society of Anesthesiologists; Ellison C. Pierce award - Best Scientific Exhibit for Patient Safety from Anesthesia Patient Safety Foundation (APSF)

The virtual anesthesia machine. Second Health Sciences Technology Fair—E-Health Science, Services, Solutions. University of Florida Health Science Center, Gainesville, Florida, March 12, 2002

Lampotang S, Liem EB, Lizdas D, Cantwell S, Modell JH: VAM technical exhibit. Annual Meeting. American College of Veterinary Anesthesiologists (ACVA). Orlando, Florida, October 10-11, 2002

APSF workbook for an anesthesia machine animation at the APSF booth; Virtual Fabius GS, v 3.0 (beta) simulation software for exhibit at Drager booth; **and** APSF anesthesia machine workbook at APSF booth. Annual Meeting. American Society of Anesthesiologists, Orlando, Florida, October 12-15, 2002

Virtual Anesthesia Machine. Internationalizing the University of Florida. The University of Florida International Center, Gainesville, Florida, November 20, 2002

Virtual Anesthesia Machine and APSF anesthesia machine workbook at APSF booth. Annual Meeting. American Society of Anesthesiologists, San Francisco, California, October 12-14, 2003

Demo of CVVH machine simulation at BBraun booth at the American Society of Nephrology meeting, San Diego, CA, November 2003

Virtual Anesthesia Machine and APSF anesthesia machine workbook at APSF booth. Annual Meeting. American Society of Anesthesiologists, Las Vegas, NV, October 24-26, 2004

Florida Society of Anesthesiologists annual conference, "Anesthesia Machine Pre-use Check", Computer Based Simulator Workshop, <u>The Breakers</u>, Palm Beach, Florida, June 25, 2005

Virtual Anesthesia Machine, APSF anesthesia machine workbook and APSF simulation of the anesthesia machine pre-use check at APSF booth. Annual Meeting. American Society of Anesthesiologists, Atlanta, GA, October 23-25, 2005

Virtual Anesthesia Machine and APSF simulation of the anesthesia machine pre-use check at APSF booth. Annual Meeting. American Society of Anesthesiologists, Chicago, IL, October 15-17, 2006

Troubleshooting the anesthesia machine **and** The anesthesia machine pre-use check **and** Preventing surgical fires **and** Using the web for anesthesia education - Here and now. University of Florida Department of Anesthesiology Winter Anesthesia Conference, Snowmass Village, Colorado. March 12, 2007

Virtual Anesthesia Machine and APSF simulation of the anesthesia machine pre-use check at APSF booth. Annual Meeting. American Society of Anesthesiologists, San Francisco, CA, October 14-16, 2007

Lampotang S, Lizdas D, Gravenstein N, Fishwick PA, Lok B: The augmented anesthesia machine. Scientific exhibit. Annual Meeting. American Society of Anesthesiologists, Orlando, Florida, October 18-22, 2008 **Third Prize Scientific & Educational Exhibit from American Society of Anesthesiologists** 

MEDICA conference, Hands-on demonstration of the mixed reality Augmented Primus anesthesia workstation, Düsseldorf, Germany, November 19 - 22, 2008

Post Graduate Assembly in Anesthesiology meeting Demonstration of the mixed reality Augmented Apollo anesthesia workstation, New York Marriott Marquis, New York, Dec 13 - 15, 2008

Lampotang S, Lizdas D: METI Human Patient Simulator Network (HPSN) Conference, Handson demonstration of the augmented reality hypoplastic left heart syndrome baby. Marriott Waterside Hotel & Marina, Tampa, Florida, March 17 - 19, 2009

Downs JB, Gravenstein N, Lizdas DE, Haines K, Luria I, Lampotang S: Pulse Oximetry, An Accurate Monitor for Detection of Hypoventilation. Annual Meeting. American Society of Anesthesiologists (ASA), New Orleans, Louisiana, October 2009 Exceptional Merit Scientific & Educational Exhibit from American Society of Anesthesiologists

UF HSC Symposium for Teaching and Learning with Technology, Simulation at the UF Academic Health Center, Communicore Building, University of Florida, Gainesville, March 10, 2011

Lampotang S, Lizdas DE, Burdick A, Luria I, Rajon DA, Schwab WK, Bova FJ, Lombard GJ, Lister JR, Friedman WA: Mixed Reality Ventriculostomy Simulator, Top Gun Contest, American Association of Neurological Surgeons Annual Meeting, Denver, CO, April 9-13, 2011

Lampotang S, Lizdas DE, Burdick A, Luria I, Rajon DA, Schwab WK, Bova FJ, Lombard GJ, Lister JR, Friedman WA: Mixed Reality Ventriculostomy Simulator, Society of Neurosurgeons Annual Meeting, Portland, OR (Presented by Drs. Lombard and Lister), May 21-24, 2011

Lampotang S, Lizdas DE, Burdick A, Luria I, Rajon DA, Schwab WK, Bova FJ, Lombard GJ, Lister JR, Friedman WA: Mixed Reality Ventriculostomy Simulator, Society of Neurosurgeons Boot Camp, Atlanta, GA (Presented by Dr. Lister), July 20-21, 2011

Lampotang S, Lizdas D, Luria I, Gravenstein N: Association for Vascular Access Annual Scientific Meeting, Subclavian Central Venous Access Simulators, San Jose, CA (Presented by David Lizdas), October 1 - 3, 2011

Lampotang S, Le H, Lizdas D, Luria I, Robinson A: Central venous top gun: clean, true, safe. Annual Meeting. American Society of Anesthesiologists, Chicago, Illinois, October 16-20, 2011 **First Prize for Best Scientific Exhibit** 

Lampotang S, Lizdas D, Luria I, Tighe P, Gravenstein N: 1st Annual Multispecialty Robotic Microsurgery Symposium Robotic Assisted Microsurgical & Endoscopic Society - RAMSES Mixed Reality Subclavian Central Venous Access Simulator, Disney's Boardwalk Resort, Lake Buena Vista, Florida (Presented by Patrick Tighe, MD), November 4 – 6, 2011

Lampotang S, Lizdas D, Luria I, Gravenstein N: Mixed Reality Subclavian Central Venous Access Simulator, International Meeting on Simulation in Healthcare, Serious Games Arcade Exhibit, San Diego, CA, January 30, 31, 2012

Lampotang S, Lizdas D, Luria I, Robinson A, Gravenstein N: Mixed Reality Subclavian Central Venous Access Simulator, Regional Conference of the Southern Group on Educational Affairs (SGEA) meeting, Lexington, KY (Presented by Albert Robinson III, MD), April 19-21, 2012

Demonstration of Central Venous Access Mixed Simulator at Interservice/Industry Simulation and Education Conference, Orlando, FL, December 6, 2012

Goldenhersh G, Ihnatsenka B, Lizdas D, Gravenstein N, Lampotang S: ASA Scientific Exhibit Mixed Reality Regional Anesthesia Simulator for Learning Psychomotor and Cognitive Skills Related to Thoracic Epidural, Thoracic Costal and Thoracic Paravertebral Nerve Blocks. San Francisco, CA, Oct 12-14, 2013 Ellison C. Pierce Award for Best Scientific Exhibit for Patient Safety from the Anesthesia Patient Safety Foundation (APSF); 2<sup>nd</sup> Prize Best Scientific Exhibit from ASA

Lampotang S, Lizdas DE: Modular mixed simulators of thoracic regional anesthesia and central venous access. International Meeting on Simulation in Healthcare, New Orleans, LA, Exhibit in Government Corral, January 11-13, 2015

Lampotang S, Gonsalves D: Hands-on demonstration of Virtual Human technology and its application to learn and practice the Agency for Healthcare Research and Quality (AHRQ) TeamSTEPPS CUS (Concerned, Uncomfortable, Safety) Speaking Up protocol including the Two-Challenge Rule at the CTSI informational booth at the College of Medicine Celebration of Research, UF Campus, Gainesville, FL, February 9, 2015

# POSTERS PRESENTED AT PROFESSIONAL CONFERENCES

# Samsun Lampotang, PhD

Gravenstein N, Lampotang S, Beneken JEW: Bain Circuit influences on capnography. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1984

Banner MJ, Lampotang S, Boysen PG, Kirby RR, Smith RA: Resistance characteristics of expiratory pressure valves. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1986

Whelan JP, Gravenstein N, Welch JL, Lampotang S, Newman RC, Finlayson B: Ventilatory effect on stone fracture during extracorporeal shock wave lithotripsy. Poster Presentation. Annual Meeting of the American Urological Association, Boston, MA, June 1988

Feldman JM, Lampotang S, Banner MJ, Gravenstein N: Effects of changes in lung model compliance on anesthesia ventilator performance. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, San Francisco, CA, October 1988

Good ML, Lampotang S, Ritchie G, Heffels J, Miller B: Hybrid lung model for use in anesthesia research and education. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, New Orleans, LA, October 1989

Good ML, Gravenstein N, Lampotang S, Blackshear R: Severity of expiratory valve incompetence (EVI) alters minimum inspired carbon dioxide (PMICO<sub>2</sub>) and capnogram. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1990

Lampotang S, Nyland ME, Gravenstein N: The cost of wasted anesthetics. Poster presentation. Annual Meeting of the International Anesthesia Research Society, San Antonio, TX, 1991

Banner MJ, Good ML, Gravenstein JS, Mahla ME, White SE, Lampotang S, Carovano RG: Matching learning style of anesthesiology residents to learning environment improves learning. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1992

Good ML, Gravenstein JS, Mahla ME, White SE, Banner MJ, Carovano RG, Lampotang S: Can simulation accelerate the learning of basic anesthesia skills by beginning anesthesia residents? Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1992

van Meurs WL, Beneken JEW, Good ML, Lampotang S, Carovano RG Jr, Gravenstein JS: Physiologic model for an anesthesia simulator. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1993

Gravenstein D, Lampotang S, Gravenstein N, Brooks M: Noninvasive hemoglobinometry. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, San

Francisco, CA, October 1994

Lampotang S, Chen BX, Good ML: Ventilator performance without a bellows: an explanation. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1996

Chen BX, Lampotang S, Good ML: Ohmeda 7800 ventilator performance with and without bellows. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1996

van Oostrom JH, Lampotang S: Non-invasive detection of dual expiratory time constants caused by unilateral lung disease. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, October 1996

Lampotang S, Gravenstein D, Melker RJ: A plastic optical fiber imaging stylet: preliminary performance data on humans, Poster presentation. Joint Meeting of the Society for Technology in Anesthesia & The Rochester Simulation Symposium: Simulation in Anesthesia. Tucson, AZ, January 14 – 17, 1998

Thoman WJ, Lampotang S, Gravenstein D, van der Aa J: An ICP model for the human patient simulator. Poster presentation. Joint Meeting of the Society for Technology in Anesthesia & The Rochester Simulation Symposium: Simulation in Anesthesia. Tucson, AZ, January 14 – 17, 1998

Gravenstein D, Lampotang S, Melker RJ: Performance of a plastic optical fiber imaging stylet for human tracheal intubation. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Orlando, FL, October 1998

Lampotang S, Gravenstein D, Melker RJ: A plastic optical fiber imaging stylet: mechanical design and preliminary experience. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Orlando, FL, October 1998

Hall JM, Lampotang S, Thoman J, Chen P, Gravenstein D, Gravenstein N: A continuous respiratory rate monitor derived from the optoplethysmogram of a pulse oximeter: Clinical Evaluation. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Orlando, FL, October 1998

Thoman WJ, Lampotang S, Gravenstein D, van der Aa J: Autoregulation mediated by oxygen demand/supply in a brain model. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Orlando, FL, October 1998

Lampotang S, Cheung-Seekit C, Langevin PB: Synchronization of chest x-ray imaging with peak lung inflation. Poster presentation at the Society for Technology in Anesthesia meeting, Hotel Del Coronado, San Diego, CA, January 20 -23, 1999

Lampotang S, Dobbins W, Good ML, Gravenstein N, Gravenstein D: Interactive, Web-based

simulation of an anesthesia machine. Poster presentation at the Society for Technology in Anesthesia meeting, Orlando, FL, January 2000

Liem EB, Lizdas DE, Lampotang S: A Model-Based Computer Simulation of Anesthesia Machine Gas Flows. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, New Orleans. LA, October 2001

Lampotang S, Cantwell S, Lizdas DE, Liem EB, Modell JH: Veterinary Use of a Free Web-Based Interactive Anesthesia Machine Simulation. Poster presentation. American College of Veterinary Anesthesiologists (ACVA) annual meeting, Orlando, FL, October 2003

Lampotang S, Liem EB, Lizdas DE, Gravenstein N: Poster Presentation. 14th International Conference on College Teaching and Learning, Jacksonville, Florida, April 4, 2003

Lampotang S, Liem EB, Lizdas DE, Nyland ME, Gravenstein N: The Virtual Anesthesia Machine: An Experiment in Sustainable Philanthropic Education over the Web. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists. San Francisco, CA, October 2003

Lampotang S, Paulus DA, Gravenstein N: FDO2 Accuracy When Supplying Nasal Cannulae from Common Gas Outlets. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Las Vegas Convention Center, Las Vegas, NV, October 25, 2004

Robicsek SA, Lizdas DE, Gravenstein N, Lampotang S: "Audible indicator of exhalation improves delivered tidal volume during bag valve mask ventilation of a patient simulator". Poster Presentation. International Anesthesia Research Society (IARS) meeting. Honolulu, Hawaii, March 11-15, 2005

Lampotang S, Moon S, Carr R, Lizdas DE, Feldman JM, Zhang R: Anesthesia Machine Pre-Use Check Survey – Preliminary Results. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, World Congress Center, Atlanta, Georgia, October 24, 2005

Zhang RV, Posey RJ, Schmeck A, Lampotang S: Evaluation and Comparison of the Hotline Fluid Warmer and the Belmont Instrument Buddy Fluid Warmer, Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, World Congress Center, Atlanta, Georgia, October 24, 2005

Wendling AL, Lampotang S, Lizdas DE, Gravenstein N, Zumberg M, Zhang RS, Sidi A, Bjoraker D: Transparent Reality Simulation of Perioperative Hemostasis: Preliminary Development and Implementation. 6th Annual International Meeting on Medical Simulation, Sheraton San Diego Hotel and Marina, San Diego, California, January 14-17, 2006

Lampotang S, Lizdas DE: Applying learning object principles to simulation: the anesthesia machine pre-use check. 6th Annual International Meeting on Medical Simulation, Sheraton San Diego Hotel and Marina, San Diego, California, January 14-17, 2006

Wendling AL, M, Zhang RS, Lampotang S, Lizdas DE, Gravenstein N, Bjoraker D, Sidi A: A novel, interactive, internet-based simulation of perioperative coagulation. Annual meeting Society for Medical Simulation (IMMS), San-Diego, California, June 2006 Wendling AL, Sidi A, Zumberg M, Zhang RS, Lizdas DE, Gravenstein N, Bjoraker D, Lampotang S: An interactive, web-disseminated, clinical simulation of perioperative coagulation for Liver Transplantation. European Society of Simulation (SESAM), Porto, Portugal, June 2006

Lampotang S, Lizdas DE, Carr RM, Mahla ME, Feldman JM: Preliminary evaluation of a transparent reality simulation of the anesthesia machine pre-use check. Poster presentation at the Annual Meeting of the American Society of Anesthesiologists, Chicago, IL, October 16, 2006

Fischler I, Kaschub C, Lizdas D, Lampotang S: Facilitating Learning of Complex Systems via Transparent Reality Simulation, Poster Presentation, 19th Annual Convention of the Association for Psychological Science Meeting, Washington DC, May 25, 2007

Lampotang S, Kaschub CE, Lizdas DE, Fischler I: Transparent Reality Simulation Enhances Learning of Anesthesia Machine Function and Dynamics. Poster Discussion. Annual Meeting of the American Society of Anesthesiologists, San Francisco, California, October 14, 2007

Yavas S, Lizdas D, Gravenstein N, Lampotang S: Interactive web simulation of propofol and fospropofol, a new propofol pro-drug. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, San Francisco, California, October 14, 2007

Lampotang S, Lizdas DE, Gravenstein N: A panoramic display-based simulation with interactive, dynamic background. Work in progress poster presentation. International Meeting on Simulation in Healthcare. San Diego, California, January 14, 2008

Lampotang S, Kaschub CE, Lizdas DE, Fischler I: Transparent reality simulation enhances learning of anesthesia machine function and dynamics. Research Day. University of Florida College of Medicine, Gainesville, Florida, April 23, 2008

Horodyski MB, LuCante K, Escobar ED, Lampotang S, Aydog ST, Schwab W, Clark M, Gravenstein N: Intermittent cold and dry air underneath football shoulder pads assists in temperature homeostasis. Annual Meeting. American Orthopaedic Society for Sports Medicine, Calgary, Canada, July 10-13, 2008

Zheng G, Schwab W, Gravenstein N, Morey TE, Lampotang S: Heliox as Carrier Gas for Isoflurane Wash-Out. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Orlando, Florida, October 19, 2008

Lampotang S, Lizdas DE, Tumino JJ, Gravenstein N, Wilkhu H: Panoramic screen-based simulation with dynamic background. Winter Simulation Conference, Miami, Florida, December 7-10, 2008

Lampotang S, Lizdas DE, Gravenstein N: A healthcare cost simulator of anesthesia in the operating room, Work in Progress Poster Presentation, International Meeting on Simulation in Healthcare, Lake Buena Vista, Florida, January 12, 2009

Lizdas DE, Gravenstein N, Lampotang S: Transparent reality simulation of skin prepping, Work in Progress Poster Presentation, International Meeting on Simulation in Healthcare, Lake Buena Vista, Florida, January 12, 2009

Quarles JP, Lok b, Lizdas DE, Fishwick P, Gravenstein N, Lampotang S: The Augmented Anesthesia Machine: A Mixed Simulator, Poster Presentation, International Meeting on Simulation in Healthcare, Lake Buena Vista, Florida, January 13, 2009

Lampotang S, Quarles JP, Lizdas DE, Fischler I, Gravenstein N, Luria I, Fishwick P, Lok B: Mixed Simulation Improves Understanding of Medical Equipment. Poster presentation at the University of Florida College of Medicine Research Day, April 29, 2009

Matveevskii A, Lizdas D, Luria I, Cooper L, Lampotang S: Web-enabled, transparent reality simulation improves anesthesia machine pre-use fault detection. Poster Presentation. Annual Meeting. American Society of Anesthesiologists, New Orleans, Louisiana, October 18-22, 2009

International Meeting on Simulation in Healthcare, Expert Panel: The Simulation Triangle: Merging Physical, Virtual and Human Simulations, Phoenix, Arizona, January 25, 2010

Zheng G, Gravenstein N, Lampotang S, Morey TE, Ben-David K: Comparison of Respiratory Effects: Heliox vs. Air/Oxygen Mixture in Laparoscopic Bariatric Surgery. Poster Presentation. Annual Meeting. American Society of Anesthesiologists, San Diego, CA, October 19, 2010

Schwab W, Lizdas D, Gravenstein N, Lampotang S: Urine drainage tubing configuration affects urinary system outflow pressure in an in vitro model. Poster presentation at the University of Florida College of Medicine Research Day, March 14, 2011

Lampotang S, Lampotang K, Lizdas D, Schwab W, Gravenstein N: Fluid–filled dependent loops in chest drainage systems impede lung re-inflation in an in-vitro model. Poster presentation at the University of Florida College of Medicine Research Day, March 14, 2011

Sidi A, Euliano T, Lampotang S, White C. Using Simulation-Based Education to Pinpoint Curriculum Deficiencies in an Anesthesiology Teaching Program. Department of Anesthesiology 2011 Celebration of Research, Gainesville, University of Florida; Poster #8, May 26, 2011 (Presented by Sidi)

Schwab W, Lizdas D, Gravenstein N, Lampotang S: Urine drainage tubing configuration affects urinary system outflow pressure in an in vitro model. Poster presentation at the Department of Anesthesiology Celebration of Research, Gainesville, University of Florida, May 26, 2011 (Presented by Dr. Schwab)

Lampotang S, Lampotang K, Lizdas D, Schwab W, Gravenstein N: Fluid–filled dependent loops in chest drainage systems impede lung re-inflation in an in-vitro model. Poster presentation at the Department of Anesthesiology Celebration of Research, Gainesville, University of Florida, May 26, 2011

Sidi A, Euliano T, Lampotang S, White C: Using simulation-based education to pinpoint curriculum deficiencies in an anesthesiology teaching program. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Chicago, IL, October 15, 2011

Sidi A, Berkenstadt H, Ziv A, Euliano T, Lampotang S, White C: Evaluating construct validity of simulation-based OSCE for summative assessment in an anesthesiology teaching program. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Chicago, IL, October 15, 2011

Schwab W, Lizdas D, Gravenstein N, Lampotang S: Urine drainage tubing configuration affects urinary system outflow pressure in an in vitro model. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Chicago, IL, October 17, 2011

Lampotang S, Lampotang K, Lizdas D, Schwab W, Gravenstein N: Fluid–filled dependent loops in chest drainage systems impede lung re-inflation in an in-vitro model. Poster Presentation. Annual Meeting of the American Society of Anesthesiologists, Chicago, IL, October 17, 2011

Robinson A, Gravenstein N, Cooper L, Luria I, Lizdas D, Lampotang S: Subclavian Central Venous Access Mixed Reality Simulator: Preliminary Experience. Poster Discussion. Annual Meeting of the American Society of Anesthesiologists, Chicago, IL, October 18, 2011

Lampotang S, Lizdas DE, Luria I, Schwab WK, Robinson A, Gravenstein N: A Mixed Simulator for Subclavian Central Venous Access. Poster presentation at the International Meeting on Simulation in Healthcare, San Diego, CA, January 30-31, 2012

Lampotang S, Lizdas DE, Burdick A, Luria I, Rajon DA, Schwab WK, Bova FJ, Lombard GJ, Lister JR, Friedman WA: A Mixed Simulator for Ventriculostomy Practice. Poster presentation at the International Meeting on Simulation in Healthcare, San Diego, CA, January 30-31, 2012

Gibby GL, Lizdas DE, Lampotang S: Profiled Vessel Model for Simulating Bladder Cystometrogram. Poster presentation at the International Meeting on Simulation in Healthcare, San Diego, CA, January 30-31, 2012 (Presented by Dr. Lampotang)

Pitkin AD, Lizdas DE, Lampotang S: An educational simulation of hypoplastic left heart syndrome. Poster Discussion. Society for Pediatric Anesthesia/American Association of Pediatrics Pediatric Anesthesiology Winter meeting, Tampa, FL, February 23-26, 2012 (Presented by Dr. Pitkin)

Lampotang S, Danek G, Lizdas D, Gravenstein N: Prevalence of dependent loops in urine drainage systems in hospitalized patients. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012

Gibby G, Lizdas D, Lampotang S: Profiled vessel model for simulating bladder cystometrogram. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012. (Presented by Dr. Lampotang)

Hooten K, Lister R, Lombard G, Lampotang S, Bova F, Rajon D, Murad G: Testing and validation of the University of Florida Ventriculostomy simulator. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012

Lampotang S, Lizdas D, Burdick A, Luria I, Rajon D, Schwab W, Bova F, Lombard G, Lister R, Friedman W: A mixed simulator of ventriculostomy practice. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012

Lampotang S, Lizdas D, Luria I, Schwab W, Robinson A, Gravenstein N: A mixed simulator for subclavian central venous access. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012

Pitkin A, Lizdas D, Lampotang S: An educational simulation of hypoplastic left heart syndrome. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012 (Presented by Dr. Pitkin)

Lampotang S, Luria I, Schwab W, Lizdas D, Gravenstein N: Simulator-based study of the Drager Apollo Low Flow Wizard. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012

Robinson A, Gravenstein N, Cooper LA, Luria I, Lizdas D, Lampotang S: Subclavian central venous access mixed reality simulator: preliminary experience. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012. (Presented by Dr. Robinson)

Chuah J, Robb A, White C, Wendling A, Lampotang S, Kopper R, Lok B: Using virtual humans for medical team training. Poster presented at the University of Florida College of Medicine Celebration of Research, March 19, 2012. (Presented by UF CISE doctoral candidate Chuah)

Lampotang S, Gravenstein N, Luria I, Lizdas DE, Schwab WK: Simulator-based study of the Drager Apollo Low Flow Wizard: Preliminary results. 15<sup>th</sup> World Congress of Anaesthesiologists, Buenos Aires, Argentina, March 28, 2012. (Presented by Dr. Lampotang)

Lampotang S, Danek G, Lizdas D, Gravenstein N: Prevalence of dependent loops in urine drainage systems in hospitalized patients. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012

Gibby G, Lizdas D, Lampotang S: Profiled vessel model for simulating bladder cystometrogram. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012 (Presented by Dr. Lampotang)

Hooten K, Lister R, Lombard G, Lampotang S, Bova F, Rajon D, Murad G: Testing and validation of the University of Florida Ventriculostomy simulator. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012

Lampotang S, Lizdas D, Burdick A, Luria I, Rajon D, Schwab W, Bova F, Lombard G, Lister R, Friedman W: A mixed simulator of ventriculostomy practice. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012

Lampotang S, Lizdas D, Luria I, Schwab W, Robinson A, Gravenstein N: A mixed simulator for subclavian central venous access. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012

Pitkin A, Lizdas D, Lampotang S: An educational simulation of hypoplastic left heart syndrome. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012. (Presented by Dr. Pitkin)

Lampotang S, Luria I, Schwab W, Lizdas D, Gravenstein N: Simulator-based study of the Drager Apollo Low Flow Wizard. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012

Robinson A, Gravenstein N, Cooper LA, Luria I, Lizdas D, Lampotang S: Subclavian central venous access mixed reality simulator: preliminary experience. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012. (Presented by Dr. Robinson)

Chuah J, Robb A, White C, Wendling A, Lampotang S, Kopper R, Lok B: Using virtual humans for medical team training. Poster presented at the University of Florida Department of Anesthesiology Celebration of Research, May 10, 2012. (Presented by UF CISE doctoral candidate Chuah)

Goldenhersh G, Gravenstein N, Bisht Y, Lizdas DE, Gravenstein M, Lampotang S: Monitoring consciousness via pulse oximeter motion artifact. Poster discussion presentation by Dr. Goldenhersh at the American Society of Anesthesiologists annual meeting, October 15, 2012

Lampotang S, Lizdas DE, Bisht Y, Luria I, Gravenstein N: An interactive iPad simulation of torso ultrasonography (Poster presentation by Lampotang); International Meeting on Simulation in Healthcare, Orlando, FL, January 27 - 30, 2013

Lizdas DE, Gravenstein N, Luria I, Lampotang S: An iPad simulation of skin prepping Abstract13th International Meeting on Simulation in Healthcare (IMSH 2013), (Poster presentation by Lampotang); Orlando FL January 27 - 30, 2013 **1st Place Award Winning Technology Innovation Abstract** 

Lizdas DE, Gravenstein N, Luria I, Lampotang S: An iPad simulation of skin prepping (Poster presentation by Lampotang); International Meeting on Simulation in Healthcare, Orlando, FL, January 28-29, 2013

Boezaart AP, Gravenstein N, Lampotang S, Lizdas DE, Nin OC, Luria I, Goldenhersh GJ, Ihnatsenka BV: Mixed reality regional anesthesia simulator for learning psychomotor and cognitive skills related to thoracic epidurals and thoracic paravertebral nerve blocks. World Congress of Regional Anaesthesia and Pain Therapy. Sydney, Australia, February 3-7, 2013

Lizdas DE, Gravenstein N, Luria I, Lampotang S: An iPad simulation of skin prepping, University of Florida College of Medicine Celebration of Research, March 11, 2013

Lampotang S Lizdas DE, Y Bisht, Luria I, Gravenstein N: An interactive iPad simulation of torso ultrasonography, University of Florida College of Medicine Celebration of Research, March 11, 2013

Goldenhersh G, Ihnatsenka B, Lizdas DE, Gravenstein N, Nin O, Lampotang S: Mixed reality regional anesthesia simulator for learning psychomotor and cognitive skills related to thoracic epidurals and thoracic paravertebral nerve blocks, University of Florida College of Medicine Celebration of Research, March 11, 2013

Goldenhersh G, Gravenstein N, Lizdas D, Bisht Y, Gravenstein M, Lampotang S: Monitoring Consciousness Via Pulse Oximeter Motion Artifact, University of Florida College of Medicine Celebration of Research, March 11, 2013

Sidi A, Baslanti TO, Gravenstein N, Lampotang S: Using simulation-based assessment to evaluate cognitive aspects of learning deficiencies in an anesthesia teaching program, University of Florida College of Medicine Celebration of Research, March 11, 2013

Sidi A, Baslanti TO, Gravenstein L, Lampotang S: Simulation-Based Evaluation for Cognitive Performance Deficiencies in an Anesthesiology Residency Training Program, Presented by Dr. Sidi at ASA 2013 poster session, October 2013

Lampotang S, Jendrusch J, Lizdas DE, Gravenstein N, Ham D, Lok B, Quarles JP: A Mixed Simulator of Ethnic Variability to Propofol during Sedation and Analgesia. International Meeting on Simulation in Healthcare, San Francisco, CA, January 25-29, 2014 <a href="http://vam.anest.ufl.edu/posters/IMSH-2014\_Race\_Propofol.pdf">http://vam.anest.ufl.edu/posters/IMSH-2014\_Race\_Propofol.pdf</a>

White C, Wendling A, Pi G, Chuah JH, Robb A, Lizdas D, Lampotang S, Lok B: A Critical Incident Scenario with Virtual Humans to Assess Patient Safety Training Needs. Selected as one of the top three research abstracts for special platform oral presentation at the David A. Paulus, MD Poster Symposium at the Florida Medical Association Annual Meeting, Orlando, FL, July 25-27, 2014

Lampotang S: CTSI Service Center in Translational Simulation in Healthcare. Poster exhibit as a new UF Clinical & Translational Science Institute core service; CTSI Town Hall meeting,

CTRB Building, UF Gainesville campus, September 23, 2014

Brunges M, Foley-Brinza C, Sullivan T, Hughes T, Skorupski D, Robb A, Cordar A, Lok B, Wendling A, Lizdas D, Gonsalves D, Williams D, Norton H, Richmond C, David D, Lampotang S: Utilizing Simulation Scenarios Involving Interdisciplinary Teams for Improving Patient Safety in the Perioperative Setting. Poster presented at the College of Medicine Celebration of Research, UF Campus, Gainesville, FL, February 9, 2015 (*poster presented by Terry Sullivan, RN*)

Lampotang S: CTSI Service Center in Translational Simulation in Healthcare. Poster presented at the CTSI informational booth at the College of Medicine Celebration of Research, UF Campus, Gainesville, FL, February 9, 2015 (poster presented by Lampotang)

Lampotang S: Mixed Reality Simulation for Training Reservists and Military Personnel in Subclavian Central Venous Access, Poster MHSRS-15-0857 presented at the Military Health System Research Conference 2015, Ft. Lauderdale, FL, August 19, 2015

#### VIDEOTAPES/VIDEOS

Samsun Lampotang, Ph.D.

Good ML, Lampotang S: The anatomy of an anesthesia machine. ASA-FDA Film Series on Patient Safety. University of Florida College of Medicine, Gainesville, Florida, 1991

Gravenstein JS, Good ML, Lampotang S, Carovano RC, Spaulding MK: The Gainesville Anesthesia Simulator. Anesthesia Patient Safety Foundation, 1991

Good ML, Lampotang S: The Human Patient Simulator. Cable News Network, Science and Technology Report (aired on CNN February 27, 1999), January 1999

Lampotang S, Lizdas DE, Gravenstein N: Video of routine rocuronium reversal with sugammadex for global launch of the UF Simulated Anesthesia Application, September 22, 2008

Production by CSSALT (Center for Safety, Simulation & Advanced Learning Technologies) of pressure sore prevention patient education video for Shands Risk management, 12/15/2010

Production by CSSALT (Center for Safety, Simulation & Advanced Learning Technologies) of Surgical Checklist video 5/19/2011

#### **GRANTS**

# Samsun Lampotang, Ph.D.

# **Currently Active Grants**

Lampotang S (PI): A Modular Set of Mixed Reality Simulators for "Blind" and Guided Procedures. Grant W81XWH-14-1-0113 \$1,750,000. TATRC/USAMRAA/DoD. August 1, 2014 – July 31, 2019

Lok B, Lampotang S, Wendling A, White C: Plug and Train: Multi-Party Mixed Reality Humans. NSF Human Centered Computing Division (medium) grant 11614914, 4-year, \$1.1 M, July 2012 – June 2016

Smith WB, Lampotang S, Gravenstein N: Retained urine volume and bacteriuria in traditional vs vented urine drainage systems. I. Heermann Anesthesia Foundation; \$80,566, July 2012 – June 2014, no cost extension

Brunges M, Sullivan T, Foley-Brinza C, Wendling A, Lampotang S: Utilizing Simulation Scenarios Involving Interdisciplinary Teams for Improving Patient Safety in the Perioperative Setting. Grant 2014845, \$55K, Blue Cross/Blue Shield Florida Blue Foundation, 2014 – 2017; awarded 12/19/13

Ihnatsenka B, Lampotang S, Edwards D: Towards a curriculum for transferrable training in thoracic epidural and paravertebral block using an advanced mixed-reality simulator. \$77,926. American Society for Regional Anesthesia, 2014 – 2015; awarded 3/28/14

White P, Lampotang S, Fahy B: Using Simulation to Train UF Health Emergency Response Teams in the ICU. \$125K, I. Heermann Anesthesia Foundation, July 2014 – June 2016

Innovated and contributed concepts and text related to simulation, innovation, integration, assessment, diversity for CTSI writing team headed by Dr. M. Limacher and tasked with drafting the Translational Workforce Development (TWD) & Team Science section for the UF CTSA/NCATS renewal proposal (~5 years, ~\$25 M); contribution of TWD team submitted to grant writing coordinators on November 6, 2014; Entire UF CTSI renewal proposal was submitted January 15, 2015 by Drs. Nelson and Conlon; (funded; ~\$20M)

Fahy B, Lampotang S: "Make It Stick: An Educational Model To Improve Long-Term Retention Of Electroencephalography Knowledge". \$100K, 2 year proposal submitted to Foundation for Anesthesia Education & Research (FAER) on 8/14/15 (funded)

## **Grants Submitted and Pending Review**

Treise, Lok, Iovine, Lampotang: Empowering patients and training clinicians about hand washing conversations before examinations. \$2.5 M, 5-yr proposal to Agency for Healthcare Research & Quality on 10/5/15 (being reviewed) *Using Virtual Humans to train and empower* 

patients to ask clinicians if they washed their hands (a CDC recommendation) and to train, desensitize and normalize clinicians to being asked by patients if they washed their hands. Agency for Healthcare Research & Quality (AHRQ) Large Research Projects for Prevention and Management of Healthcare-Associated Infections (R01); Funding level: \$2.5M over 5 years. This collaboration with Dr. Treise of the UF College of Journalism (who has studied and published on the subject of clinician handwashing and patient attitudes towards that sensitive topic) was brokered through the UF CTSI.

Ural, Lampotang: Functionalized graphene gas sensors for monitoring anesthetic gas. LOI submitted to UF Opportunity Fund on 11/23/15, invited to submit full proposal12/22/15; full 2-yr, \$99,999 proposal submitted 1/20/15

Blakemore L, Lampotang S: Development and Validation of a Simulator-Based ultrasound-Guided Aspiration Training for Orthopaedic Residents (uGATOR), LOI proposal to Gerber Foundation; \$267,070 to CSSALT, \$322K total, 3 years on 12/2/2015 (being reviewed)

## **Grants in preparation**

Moseley R, Lampotang S: Using Virtual Humans for training of research administrators, research staff and clinicians in managing ethical dilemmas in simulated research settings. R01; preliminary exploratory stage

Proposal to Draeger Medical (with Jeff Feldman, MD) for online screen-based CME as part of a pilot project of the Anesthesia Patient Safety Foundation Committee on Technology Task Force for Medical Training Device Initiative in Collaboration with Industry

#### **Grants Completed**

Good ML (principal investigator), Lampotang S (co-principal investigator): Development of an education curriculum using anesthesia simulation. Ohmeda, \$47,634, 1988-1990

Good ML (principal investigator), Lampotang S (co-principal investigator): Can simulation teach clinical skills? Anesthesia Patient Safety Foundation, \$35,000, 1989-1990

Good ML (principal investigator), Lampotang S (co-principal investigator): Medical simulation center--planning grant. Florida High Technology and Industry Council, \$18,000, 1990-1991

Good ML (principal investigator), Gibby GL (co-principal investigator), Lampotang S (co-investigator): Transesophageal echocardiography: training curriculum and patient simulator. Florida High Technology and Industry Council, \$89,000, 1990-1991

Good ML (principal investigator), Gravenstein J (co-principal investigator), Lampotang S (co-investigator): Anesthesia simulators and training devices as a learning tool for continuing medical education. Ohmeda Anesthesia Systems, \$35,244, 1990-1992

Good ML (principal investigator), Gravenstein JS (co-principal investigator), Lampotang S (co-

investigator): Anesthesia simulation. Anesthesia Patient Safety Foundation, \$95,000, 1991-1992

Good ML (principal investigator), Carovano R (co-principal investigator), Lampotang S (co-investigator): Medical simulation center, operational phase. Florida High Technology and Industry Council, \$48,067, 1992-1993

Good ML (principal investigator), Paulus DA (co-principal investigator), Lampotang S (co-investigator): Transesophageal echocardiography: training curriculum and patient simulator. Hewlett-Packard, \$41,250, 1992-1993

Good ML (principal investigator), Lampotang S (co-investigator): Anesthesia simulation. Anesthesia Patient Safety Foundation, \$95,000, 1992-1993

Melker RJ (principal investigator), Banner MJ (co-principal investigator), Lampotang S (researcher): Research and development of transportable ventilators and monitoring systems. Life Support Products, Inc, \$66,075, 1992-1993

Good ML (principal investigator), Gravenstein JS, Lampotang S (co-principal investigators): Hardware and curriculum development for the State of Florida medical patient simulator. Florida Department of Education (\$200,000), 1993

Banner MJ (principal investigator), Blanch PB, Kirby RR, Lampotang S (co-principal investigators): Effects of the rate of pressure rise on work of breathing during pressure support ventilation. Bear Medical Systems, Inc, \$4,625, 1993

Gravenstein D (principal investigator), Gravenstein N (co-principal investigator), Lampotang S, Sultan A, Melker R (co-investigators). Gatorade Allocation to Support the Further Development of the Method for Light and Sound Conduction Through the Trachea. University of Florida, Division of Sponsored Research, \$25,000, 1993

Gravenstein D (principal investigator), Gravenstein N (co-principal investigator), Lampotang S, Atwater J, Brooks M (co-investigators): Noninvasive hemoglobinometry. BlackBox, \$2,000, 1993

Good ML (principal investigator), Carovano R (co-principal investigator), Lampotang S (co-investigator): Medical simulation center operational phase. Florida High Technology and Industry Council, \$48,828, 1993-1994

Lampotang S (principal investigator), Gravenstein JS (co-principal investigator): Gainesville recirculating anesthesia delivery system (GRADS). Hewlett Packard Corporation, \$177,187, 1993-1994

Melker RJ (principal investigator), Banner MJ, Lampotang S (co-principal investigators): Research and development of transportable ventilators and monitoring systems-extension. Life Support Products, Inc., \$155,508, 1993-1994

Good ML (principal investigator), Lampotang S (co-principal investigator): Mount Sinai simulator project: research and prototype production. Mount Sinai Medical Center, \$150,000, 1993-1994

Lampotang S (principal investigator), Good ML, Gravenstein JS, van Meurs W (co-principal investigators): Simulator-based usability study of an automated anesthesia record keeper. Datex Medical Instrumentation, \$30,676, 1994

Lampotang S (principal investigator): Hardware enhancements for the Loral Human Patient Simulator. Loral Data Systems, \$25,000, 1994-1995

Lampotang S, (principal investigator), Melker R, Gravenstein N, Gravenstein D (co-principal investigators): Gatorade Allocation to Support Further Development of the Method for Light and Sound Conduction Through the Trachea. University of Florida, Division of Sponsored Research, \$17,000, 1995

Lampotang S (principal investigator), Melker R (co-principal investigator): Electronic gas blender project. Allied Healthcare Products, \$86,461, 1995

Lampotang S (principal investigator), van Oostrom H, Gravenstein JS (co-principal investigators): Gainesville recirculating anesthesia delivery system (GRADS). Hewlett Packard Corporation, \$160,150, 1994-1995

Lampotang S (principal investigator), Good ML (co-principal investigator): Simulator-based usability study of the Datex Record Keeper II. Datex Medical Instrumentation, \$18,000, 1995

Lampotang S (principal investigator): Travel award. University of Florida Division of Sponsored Research, \$4,000, 1995

Lampotang S (principal investigator), van Oostrom H (co-investigator): Pilot HPS-MedSAF data link. Science Applications International, Inc., \$11,465, January 1996-February 1996

Lampotang S (principal investigator), Euliano TY (co-principal investigator): Usability study of the Johnson & Johnson integrated physiological monitor. Johnson & Johnson Medical Instrumentation, \$18,526, 1996-1997

Lampotang S (principal investigator): Graduate Research Assistantship Award. University of Florida Division of Sponsored Research, \$5,768, 1996 (0% FTE)

Lampotang S (principal investigator): Gap funding. Office of Research Technology and Graduate Education, \$16,933, 1996 (10% FTE)

Lampotang S (principal investigator), Banner MJ (co-principal investigator): Performance evaluation of an active heat and moisture exchanger using research dogs. Gibeck, \$48,142,

1996-1997

Lampotang S (principal investigator), van Oostrom JH (co-principal investigator): Extraction of breath rate from the pulse oximeter optoplethysmogram. Novametrix Medical Systems, \$67,585, 1996-1997

Lampotang S (principal investigator), Gravenstein D (co-principal investigator): Improved retention of critical neuroanesthesia concepts learned using a patient simulator compared with didactic teaching. I Heermann Anesthesia Foundation, \$7,500, 1997-1998

Lampotang S (principal investigator), Mason P, Gravenstein N, Reisinger K, Gravenstein D (coprincipal investigators): A cervical motion sensor for the Human Patient Simulator. University of Florida BioMedical Engineering Program, \$6,242, November 1998-April 1999

Lampotang S, Liem EB: Virtual Fabius GS project. Drager Medical Inc. \$22,000, 2001

Lampotang S (principal investigator), Liem EB (co-principal investigator): Enhancements to the Virtual Fabius GS. Drager Medical, Inc., \$25,000, Fall 2001

Lampotang S (principal investigator), Gravenstein JS (co-principal investigator): Development of an anesthesia machine workbook. Anesthesia Patient Safety Foundation, \$15,000, 2002

Lampotang S (principal investigator): Additional Enhancements to the Virtual Fabius GS. Drager Medical, Inc., \$27,500, 2002

Lampotang S (principal investigator): Internationalizing the Curriculum for VAM. University of Florida Academic Technologies, \$3,000, 2003

Lampotang S: Support for web simulation from the University of Florida Distance and Continuing Education – web simulation of CVVH-dialysis and – filtration, \$50,000, 2003-2004

Lampotang S (principal investigator): Effectiveness of the Virtual Anesthesia Machine web simulation as a learning tool. I. Heermann Anesthesia Foundation (IHAF). \$30,000, 2003-2004

Lampotang S (principal investigator), Gravenstein N (co-principal investigator): Simulator based study of the Anaconda vaporizer. Hudson RCI, \$37,500, May-July 2004

Lampotang S (principal investigator): Use of instructor VAM to teach general anesthesia with volatile anesthetics in Japan. Abbott Laboratories. Japan. \$4,500, July 2004 - June 2005

Lampotang S: Support for web simulation from the University of Florida Distance and Continuing Education, \$55,000, July 2004- June 2005

Lampotang S (principal investigator): Factor 7 Web Simulation and Web Site. Novo Nordisk, \$50,000, 2004-2005

Lampotang S (principal investigator): Development and evaluation of simulation and workbook for the anesthesia machine pre-use check. Anesthesia Patient Safety Foundation, \$75,000, 2005

Lampotang S (principal investigator), Gravenstein N, Dryden P: Smart Self-Inflating Resuscitation Bag – UF#11487, University of Florida Research Foundation Commercialization Fund, \$9,000, 2005

Lampotang S (principal investigator): Development of a web-enabled simulation of carbon dioxide absorption in an anesthesia circle system. Molecular Products, \$9,000, 2005

Lampotang S (principal investigator) International Business Machines (IBM) Faculty Award, \$10,000, 2005

Berger JJ (principal investigator), Lampotang S, van Oostrom JH (co-principal investigators): Maren educational initiative to simulate adverse drug interactions. Thomas H. Maren Foundation, \$150,000, 2002 – 2007

Lampotang S (principal investigator), Wilkhu H, Gravenstein N: Simulated Anesthesia Experience Phase I. Organon USA, \$129,658, 2007

Lampotang S (principal investigator), Wilkhu H, Gravenstein N (co-investigators): Simulated Anesthesia Experience Phase IIA. Organon USA, \$76,497.50, 2007-2008

Lampotang S, Gravenstein N: Educational grant from Enturia. \$10,000, 2008

Lampotang S (principal investigator), Wilkhu H, Gravenstein N (co-investigators): Simulated Anesthesia Application Phase IIB. Organon USA, \$308,955, 2008 - 2011

Lampotang S: Simulation faculty learning community (SimFLC). University of Florida Office of the Provost, \$6,600, 2008

Pitkin A, Lizdas DE, Lampotang S: Development of, and evaluation of learning with, a new simulation of single-ventricle physiology. \$64,744, I. Heermann Anesthesia Foundation, 2008

Lampotang S: Organon anesthesia preceptorship. Organon, \$20,000, 2008

Gravenstein D (principal investigator), Rice M, Lampotang S (co-principal investigators): Noninvasive hemoglobin measurement. Office of Technology and Licensing, \$28,500, August 2007-December 2008

Lampotang S: Augmented Apollo and Primus. \$35,000. Dräger Medical, 2008 - 2009

Lampotang S: Simulator-Based Usability study of Automated Anesthesia Record Keeper, Philips Medical, \$16,200, 2009

Lampotang S, Gravenstein N: Simulator-Based Usability study of a new anesthesia machine design. \$24,973, Maquet, Sweden, 2009

Lampotang S, Gravenstein N: Support for Global Simulated Anesthesia Application, \$9,250, Schering Plough, 2009 – 2010

Lampotang S: Augmented Apollo Demonstration Project, \$10,000, Dräger Medical, 2009

Lampotang S, Graventein N: Translation and Support of the Simulated Anesthesia Application. \$101,800, 2009 – 2010

Lampotang Gravenstein N: Simulated Anesthesia Application, \$17,500, Schering Plough/Merck, 2009 - 2010

Lampotang S, Gravenstein N: Development of a skin prep simulator. \$50,000, CareFusion, 2009-2010

Lampotang S: Ventriculostomy simulator. \$22,575, UF Neurosurgery Department, 2010 – 2011

Lampotang S, Gravenstein N, Luria I: Production of a patient education video for pressure sore prevention to be aired on Shands in-house TV channel. Shands Self-Insurance Program, \$5,000, 2011

Sidi A, Euliano T, Lampotang S, White C: Using Simulation-Based Education to Evaluate Curriculum Deficiencies and Improve Non-Technical Skills, in an Anesthesiology Teaching Program. University of Florida, College of Medicine, Chapman Education Center (COMCEC), Faculty Educational Research Grants; \$5,000, July 2011

Lampotang S, Gravenstein N: Skin prep simulator. \$50,000, CareFusion, 2011 – 2012

Lampotang S, Gravenstein N, Schwab WK: Simulator-based study of Apollo Low Flow Wizard, \$40,000, Dräger Medical, 2011 - 2012

Lampotang S, Gravenstein N: Subclavian central venous access simulators. TeleFlex Medical, \$100,000, 2011- 2013

Lampotang S, Lizdas D: Service Agreement with TeleFlex for Spare Tracked Central Venous Access Needles: \$2,000, funding received June 5, 2012

Lampotang S, Gravenstein N: Simulator-based usability study of medical equipment, Philips Healthcare, \$60,813, 2012-2013

Lampotang S: Simulator-based usability study of medical equipment, Maquet, \$50,000, 2013

Lampotang S: Design and build a mixed simulator of regional anesthesia. \$60K. TeleFlex, 2013-2014

Lampotang S: Repair of CVA mixed simulator #1. \$9,600. TeleFlex Medical, 2014

Lampotang S: Repair of CVA mixed simulator #2. \$5,262. TeleFlex Medical, 2014

Quarles JP, Lampotang S, Lok B, Gravenstein N: A Mixed Reality Conscious Sedation Simulator for Learning to Manage Variability, 1R21LM010829-01A1 NIH/NLM; National Library of Medicine, National Institutes of Health, \$369,473; 2011 – 2013

Lampotang S, Gravenstein N: R&D for management and mitigation of undrained dependent loops. \$20K; University of Florida Office of Technology Licensing Commercialization Fund, 2010 - 2012

Ihnatsenka B, Lampotang S: Mixed reality regional anesthesia simulator. \$83,370, I. Heermann Anesthesia Foundation, 2011 - 2013

Lampotang S, Gravenstein N: iPad 2 App for Simulation of CareFusion ChloraPrep Skin Prep \$50,000; CareFusion, 2012- 2013

Le-Wendling, Gravenstein D, Matthie, Lampotang, Lizdas, Enneking: Venous Air Embolism (VAE): A Widespread and Likely Fatal Complication and the Development of a Multidisciplinary Simulation Model for the Education of the Physiology, Detection and Management of VAE, \$25,000, 2012-2013

#### **Grants Submitted but not Funded**

Lampotang S, Fischler I, Beck H, Euliano T: The science of learning with simulation - UF Medical Simulation Center. \$100,000 submitted to UF RGP Opportunity Incentive Seed Fund on 1/18/2004 (*declined*)

Lampotang, S, Gravenstein N: Abbott Laboratories - Web education on sevoflurane fires - \$100,000, submitted 2/16/2004 (*declined*)

Lampotang S, Gravenstein N: Web simulation, web site and curriculum for aprotinin. Bayer. \$150,000, submitted 2/18/04 (*declined*)

Lampotang S, Liem EB: Educational simulation of the Glidescope video laryngoscope, Saturn Medical, \$15,000, submitted 7/04 (*declined*)

Lampotang S: Proposal to Molecular Meds for the simulation of CO<sub>2</sub> absorption \$29,500. Submitted 12/16/04 (*declined*)

Lampotang S (PI), Fischler I, Beck H, Su S, Legg SM: Center for the Science of Learning with Simulation. A 10-year, up to \$50M proposal to NSF submitted on 2/24/2005 (*declined*)

Su SY (PI), Lampotang S (co-PI): Dynamic and collaborative e-learning technologies and their application and assessment in medical simulation and instruction. \$182,425 for Anesthesia

share out of \$559,864 total submitted to NSF Advanced Learning Technologies on May 2005 (declined)

Su SY (PI), Lampotang S (co-PI): A Learner-centered interactive and dynamic e-learning technology for instruction and learning. \$168,054 for Anesthesia share submitted to NSF Advanced Learning Technologies on 4/28/2006 (declined)

Lampotang S (PI), Fischler I, Hou W: Can simulation alter clinician risk perception and preprocedural behavior? Agency for Healthcare Research and Quality RFA-HS-06-030 Improving Patient Safety through Simulation Research. \$420,566, submitted May 2006; received a score of 248 (declined)

Lampotang S (PI), Gravenstein N: Educational, panoramic simulation of fospropofol use during conscious sedation. \$117,200, MGI Pharma (*declined*)

Werning J (PI), Lampotang S: Can Visual-Spatial Cognitive Impairments in Surgeons be Predicted and Remediated? \$20K proposal to UF CME Office – declined March 2007

Lampotang S (PI), Robinson A, Lizdas DE, Lok B: Adding mixed reality to manikin-based simulation. \$60K proposal submitted to the I Heermann Anesthesia Foundation on 5/7/2007 (declined)

Werning J (PI), Lampotang S: Can Visual-Spatial Cognitive Impairments in Surgeons be Predicted and Remediated? \$100K Letter of intent to National Patient Safety Foundation – declined July 07

Janelle C (PI, Lampotang S (co-PI): Identifying and training mechanisms of expertise in cardiothoracic anesthesiology. 2007-2009; \$20,432 submitted to National Institutes of Health (declined)

Lok (CISE), Fishwick (CISE), Lampotang, Fischler (Psychology): Educating STEM (Science, Technology, Engineering and Mathematics) concepts with collocated abstract and concrete, \$487,184 proposal to NSF Advanced Learning Technology program; (Dept. of Anesthesiology share \$55,834); declined 8/16/07

Lampotang (PI): \$100,000 proposal submitted to MGI Pharma for panoramic simulation of conscious sedation on 3/27/2008 (*declined*)

Lampotang (PI): Educational panoramic simulation of fospropofol use during conscious sedation. \$117,200 proposal submitted to MGI Pharma on April 15, 2008 (declined)

Lampotang (PI): Panoramic simulation of conscious sedation. \$130K proposal submitted to Eisai, Inc. on 5/8/2009 (declined)

Lampotang (PI), Paulus (co-PI): CVC Simulation and Web Site. \$200K proposal to Cook Medical submitted on 6/1/2010 (declined)

Lampotang S (PI), Fischler I (co-PI): Effects of simulation training on clinician empathy, risk perception, and checklist compliance; \$689,244 2-year Proposal to Agency for Healthcare Research and Quality - Improving Patient Safety through Simulation Research R18 RFA-HS-10-018. (declined)

Lampotang S, Rosenberg E, Fischler I, Gravenstein N, Cooper LA, Bethart S, Gindoff A, Hou W: Understanding and enhancing healthcare provider quality compliance with best practices. Project summary for a \$200K proposal submitted to Dr. Guzick for internal UF&Shands screening for Arthur Vining Davis Foundation; submitted 7/1/10 (declined)

Lampotang S: Testing of volatile anesthetic modeling on the Human Patient Simulator, Medical Education technologies, Inc., \$3,000, submitted 8/17/10 (*declined*)

Lampotang, Gravenstein N, Baylis, Hou: Hospital-acquired infection from urine-filled drainage tubes: Clinical, epidemiological and physiological investigations and evaluating potential technical and educational solutions. 2-year, \$99,592 Letter of Intent submitted to NPSF on 9/9/10 (declined)

Lampotang, Gravenstein N, Baylis, Hou: Hospital-acquired infection from urine-filled dependent loops in drainage tubes: Clinical, epidemiological and physiological investigations and evaluating potential technical and educational solutions; \$100,000; 1-page letter of intent submitted to UF College of Medicine as part of UF Opportunity Fund on 10/29/10 (declined)

Janelle C, Lampotang S, Gravenstein N, Janelle G: Identification and training of psychomotor mechanisms underlying expertise in cardiothoracic anesthesiology. R18 Proposal in Response to Agency for Healthcare Research and Quality's Advances in Patient Safety through Simulation Research Program Announcement PAR-11-024. \$202,244 to Anesthesia – submitted 1/21/11 (declined)

Lampotang S, Gravenstein N: Does the absence of urine-filled loops in urine drainage tubing decrease Catheter Associated Urinary Tract Infections? \$25,000 submitted to UF CTSI grant program on 1/26/11 (declined)

Lampotang S (PI): Does the absence of dependent loops in urine drainage tubing decrease catheter associated urinary tract infection? 2-year R21 proposal to NIDDK/National Institutes of Health, \$402,875, submitted 2/16/11 – received score of 43 (declined)

White C, Lampotang S, Lok B: Virtual Humans as Pinch Hitters for Simulation Team Training on Transfer of Care, \$100,000; proposal submitted to I. Heermann Anesthesia Foundation on 3/18/11 (declined); similarly themed proposal (Virtual Humans as Pinch Hitters for Simulation Team Training) was eventually funded as 4-yr, \$1.1 M NSF grant with Lok as PI and Lampotang as CoM PI

Lampotang S, Gravenstein N: Skin prep simulator, web site, credentialing and study. 5-year, \$625K proposal to CareFusion; submitted 6/2/11 (declined)

Lampotang S, Gravenstein N: CVL simulators; \$200K, TeleFlex Medical; submitted 6/13/11 (declined)

Lampotang S: Ventriculostomy simulator. \$30K, Henry Ford Hospital; submitted 6/17/11 (declined)

Lampotang S, Gravenstein N: Scaled down skin prep simulator, web site, credentialing and study. \$125K proposal to CareFusion; submitted 6/17/11 (declined)

Lampotang S: Skull only ventriculostomy simulator. \$4,310, Henry Ford Hospital; submitted 6/23/11 (*declined*)

Lampotang, Danek, Gravenstein N, D'Angelo, Moy, Lizdas: Web-enabled simulation for improving low compliance with Shands CAUTI prevention policy of avoiding dependent loops, \$49,347; submitted to UF&Shands Clinical Quality Award program on 12/23/11 (declined)

\$2,675 (no IDC) proposal to UF NeuroSurgery Department for adding a new inner brain to the ventriculostomy simulator; submitted 2/24/12 (declined)

Proposal (3-yr, \$275K proposal to improve pain education in all 4 years of medical school – PI: Hurley) to Altarum Institute/Palladian Partners REQUEST FOR PROPOSALS National Institutes of Health Pain Consortium Centers of Excellence in Pain Education (CoEPEs) Fundamentals of Pain Medicine; submitted 3/5/12 (declined)

Proposal to Covidien for clinical study on TopVent urine drainage system; submitted 3/23/2012 (declined)

Proposal to Philips for a screen-based simulator, \$93,479; submitted 4/28/2012 (declined)

Weiss M, Douglas-Escobar M, Lampotang S: Using social media and the web to disseminate best practices for managing neonatal brain injury. AHRQ 3-year, \$900K proposal; submitted 5/22/2012 (declined)

Key personnel on NIH T32 by Dore and Hurley: Training in Neuroscience in Perioperative and Critical Care Medicine; submitted 5/25/12 (*declined*)

Lampotang, Gravenstein N. Lizdas: Proposal to Clinical Quality Award program: Web-enabled simulation for improving low compliance with Shands CAUTI (Catheter Associated Urinary Tract Infection) prevention policy of avoiding dependent (hanging) loops in urine drainage tubing; \$49,347; submitted June 1, 2012 (declined)

\$239K proposal submitted to TeleFlex for simulation deliverables for central venous access, submitted July 13, 2012 (*declined*)

Study protocol for TopVent urine drainage study, \$82,237, submitted to Covidien on August 15,

2012 (*declined*)

\$40K proposal submitted to Drager for study comparing wash-out and wash-in in Perseus and Avance anesthesia machines. September 4, 2012, (declined)

Douglas-Escobar M (PI), Lampotang (co-investigator) \$300K; \$100K per year over 3 years (\$120K total for David Lizdas): Proposal submitted to March of Dimes September 10, 2012, (declined)

Proposal (\$70,000) for simulator-based usability study submitted to Scott Hunsaker, Covidien October 5, 2012, (declined)

Proposal \$123,749 submitted to Walter Huehn, Philips for Philips AX700 IntelliSave Anesthesia Machine Simulator October 5, 2012 (*declined*)

Lampotang, Lesko, Schmidt, Derendorf, Gravenstein N: \$100K LoI to CoM for proposal Patient Variability Modeling & Simulation as Clinical and Translational Science, submitted October 30, 2012 (declined)

3-yr proposal submitted May 22, 2013 to AHRQ – Neff D, Lampotang, Stechmiller - Simulation Team Training for Timely Intervention during Respiratory Deterioration - Sponsor Name: AGCY HEALTHCARE RES & QUALITY (AHRQ): Start Date: 04/01/2014 End Date: 03/31/2017 (declined)

T-32 proposal submitted to NIH NINDS on May 25, 2013 – PI: Dore and Hurley, Lampotang Role Senior Mentor - Training in Neuroscience of Perioperative and Critical Care Medicine (*declined*)

\$40K proposal to TeleFlex for upgrade (addition of simulated US guidance and other features) of 2 Central Venous Access (CVA) mixed reality simulators originally supplied by UF. Submitted September 13, 2013 (declined)

Sappenfield, Lampotang: Society for Simulation in Healthcare \$5K starter grant. Mentor to Josh Sappenfield. Submitted September 20, 2013 (declined)

AHRQ R18 proposal *Simulation Team Training for Timely Intervention During Respiratory Deterioration*. Submitted as co-investigator; re-submitted with the College of Nursing Dean Anna McDaniel as PI instead of Neff who moved to UCF, September 24, 2013 (*declined*)

Proposal to Alaris, CareFusion "Clinical study of safety and efficacy of an even Smarter Alaris pump" for \$187,500 emailed to Igor Nesterenko on October 1, 2013 (*declined*)

High performance graphene-based nanoscale gas sensors for anesthesia monitoring; \$100K; UF Opportunity Fund. Ural A, Lampotang S. Submitted November 21, 2013, (declined)

Ihnatsenka, Lizdas, Lampotang: Curriculum development and validation study for a regional

anesthesia simulator, \$125K proposal submitted to I. Heermann Anesthesia Foundation (IHAF) on January 17, 2014 (*declined*)

Caruso. Lizdas, Lampotang: The Effect of color-coding anesthesia medication labels on the incidence of medication administration errors, \$125K proposal submitted to I. Heermann Anesthesia Foundation (IHAF) on January 17, 2014 (declined)

Hurley (PI): Anesthesiology NIH/NIGMS T32 application titled "Research Training Program in Perioperative, Critical Care and Pain Medicine"; Lampotang (consultant); January 25, 2014 (declined)

Lampotang, Gravenstein: \$150K, 2-yr proposal "Reducing IV pump alarms via patient empowerment and participation" submitted to Anesthesia Patient Safety Foundation on March 3, 2014 (declined)

NIH/NIDDK R21 proposal re-submitted. PI Lampotang; co-Is: Smith, Gravenstein N, Wishin, Moy (Urology), Zou (Biostatistics); Rand (Epidemiology): Does venting dependent loop backpressure reduce urine retention and bacteriuria? \$412,500 over 2 years, submitted March 17, 2014 (declined)

Steadman R (UCLA), Schwid H (UCI), Taekman J (Duke), Lampotang S, UCLA CRESST group: Proposal to ASA for online MOCA 2.0, \$0.4 - 1.0M, submitted June 26, 2014 (declined; ASA will issue an RFP instead)

Proposal to Covidien for applying UF IP on patient empowerment technology during capnography for procedural sedation; submitted September 9, 2014 (*declined due to merger discussions with Medtronic*)

Ural/Lampotang: Anesthesia gas sensors based on graphene. Letter of Intent to UF Research Opportunity Fund 2015, submitted November 19, 2014 (declined)

Lampotang S, Pillai K, Murad F: Dosing practices during propofol sedation: awareness, and clinical data collection, of race-specific propofol pharmacodynamics in the multi-racial population of Mauritius. Submitted January 15, 2015 in collaboration with clinicians and researchers from Apollo Bramwell Hospital, Mauritius to Astra Zeneca through Dr. J. Bhana, Vice President: Medical and Regulatory Affairs, South Africa and Sub Saharan Africa, Astra-Zeneca (declined)

Lok B, Lampotang S, Wendling A, White C: Positive "Virtual" Peer Pressure - Influencing Best Practices to Improve Patient Safety with Mixed Reality Human Training. Grant period: 1/1/16 – 12/31/18. Funding level: \$750,000. R18 proposal submitted to Agency for Healthcare Research & Quality (AHRQ) on January 26, 2015 (declined)

Przkora R, Lampotang S: Using Virtual Humans for training anesthesiologists in affective skills for managing difficult patients. Anesthesia Patient Safety Foundation: Funding level: \$150,000 over 2 years, Letter of Intent submitted March 2, 2015 (declined)

Lampotang, Lizdas, Gravenstein: Screen-based Maintenance of Certification in Anesthesiology 2.0 (MOCA 2.0) \$2.4M, 4-yr proposal presented to ASA Board of Directors, Chicago. IL on 8/16/15 (finalist but declined)

Butler K, Koppal SJ, Lampotang S, Rashidi P, Tighe P: Patient Privacy and Safety in the Intelligent Operating Room, \$100K, 1-year, University of Florida proposal submitted to Microsoft on 9/5/15 (*declined*)

# **VAM Website Sponsorship**

AirTraq/ProMedic \$10,000, 5/15/08 – 5/14/09

Galemed \$10,000 for period 6/15/07 - 6/14/08

Storz, \$10,000 for period 6/1/08 - 5/31/09

WFSA, \$1,000, December 07-November 08

Storz, \$10,000, August 6 2007-August 5, 2008

GE Healthcare, \$10,000, July 1, 2007-June 30, 2008

AirTrag/ProMedic \$10,000 5/15/07 – 5/14/08

Enturia, \$10,000, 5/1/07 – 4/30/08

Maren Foundation, \$10,000, April 2007 – March 2008

Molecular Products, \$4,000, January 12, 2007-January 11, 2008

WFSA, \$1,000, December 06-November 07

Galemed \$9,980 for period 6/15/06 – 6/14/07

GE Healthcare, \$10,000, July 1, 2006-June 30, 2007

AirTraq/ProMedic \$10,000 5/15/06 – 5/14/07

Galemed \$10,000 for period 6/15/05 - 6/14/06

Lampotang S: Sponsorship of VAM web site. Datex-Ohmeda. \$10,000, 2003-2004

Lampotang S: Support of VAM web site. Movit. \$2,200, 2003

Lampotang S: Sponsorship of VAM web site. Drager Medical Inc. \$10,000, 2002-2003

## **Donations**

United Nations International School, \$50.00, 2007

Donation to the Virtual Anesthesia Machine project from Mr. James H. Lybass and Mrs. Joh-Nana Lybass, \$18,500, 2008.

Bobbi Bergmooser, \$25.00, 2008

Dr. Robert and Mrs. Rosita Williams, \$40,000, December 2010

# **Bequests**

\$250,000 to the Center for Safety, Simulation & Advanced Learning Technologies from Dr. Robert and Mrs. Rosita Williams in 2009

Instructor VAM and Site License Subscriptions, July 1, 2007-June 30, 2008

65 subscriptions @ \$100.00/subscription, \$6,500 1 site license (Brookdale Hospital, NY), \$1,800

#### IRB APPROVALS

**IRB Project #: 76-2011**: Prevalence of Dependent Loops in Urine Drainage Systems: PI: Danek, Co-PI: Lampotang (IRB 01); valid until Feb 2012

Smith W, Wishin J, Gravenstein N, Lampotang S: IRB-01, Comparative randomized clinical trial of vented v. non-vented (traditional) urine drainage in consented patients with regards to retained urine and bacteriuria, 2014-2015

**UFIRB# 2011-U-532** Evaluate Drager Low Flow Wizard and Effects on Anesthetic Consumption and Fresh Gas Flows. PI Lampotang, Co-PI: Gravenstein N, Lizdas – renewed 2/20/12; valid until May 12, 2012 (IRB 02)

**IRB Project #: 357-2011**: Observational Prevalence Study of Dependent Loops in Chest Drainage Systems: PI: Lampotang, Co-PI: Danek (IRB01). Valid until August 9, 2012 (IRB 01)

**UFIRB# 243-2011** A Mixed Reality Conscious Sedation Simulator For Learning To Manage Variability. PI Lampotang, Co-PI: Gravenstein N, Lizdas – renewed 2/20/12; valid until 3/11/13 (IRB 02)

Revision of IRB 02 **UFIRB# 243-2011** submitted for ASA survey on propofol dosing practices and review of clinical records for propofol dosing for procedural sedation, submitted September 24, 2013

**UFIRB# 2012-U-0609:** Preliminary evaluation of a new use of an FDA-approved, non-invasive medical device to detect deliberate motion artifact. PI Lampotang, Co-PI: Gravenstein N. Valid through May 10, 2013 (IRB 02)

**UFIRB# 2012-U-0704:** Simulator-based usability study of a new anesthesia workstation. PI Lampotang, Co-PI: Gravenstein N. Valid through June 18, 2013 (IRB 02)

Robinson, Smith, Sappenfield, Lampotang: Learning outcome study on next-gen CVA mixed reality simulator IRB-02, 2013-2014

Lampotang, Chheda, Gonsalves, Gravenstein N: Efficacy of saline introduction in the oral cavity of a simulated head in the event of an airway fire; IRB02, 2013-2014

Outcome study on UF thoracic regional anesthesia simulator funded by the American Society of Regional Anesthesia (ASRA): UF IRB 2014-U-658

Fiastro, Lampotang, Gravenstein: Evaluation in volunteers of an infusion pump with an integrated verbal prompt to patients to self-clear any kinks in the intravenous line before an audible alarm occurs. 2013-2014 Protocol #2013-U-0376

Robb, Lok, Wendling. White, Lampotang: VH-enabled needs assessment of OR nurses speaking up and calling charge nurse when blood type and screen data is missing and surgeon wants to proceed with incision during simulated scoliotic surgery repair. 2012-2013

Cordar, Robb, Lok, Wendling. White, Lampotang: VH-enabled needs assessment of OR nurses speaking up and calling charge nurse when surgical count has a discrepancy and surgeon wants to proceed with surgical wound closure. 2013-2015

**HRPO Log Number A-18036** protocol "Towards a Curriculum for Transferrable Training in Thoracic Epidural and Paravertebral Block Using an Advanced Mixed-Reality Simulator" submitted for review on December 8, 2014

#### **PATENTS**

# Samsun Lampotang, Ph.D.

#### **Patents Issued**

Gravenstein JS, Lampotang S: Self-contained jet pump breathing apparatus. US Patent 4,702,241 issued October 27, 1987

Lampotang S, Gravenstein D, Gravenstein JS, Gravenstein N, Banner MJ: CO<sub>2</sub> diagnostic monitor. US Patent 4,928,687 issued May 29, 1990

Banner MJ, Blanch PB, Lampotang S. Co-designed an adult/pediatric transport ventilator marketed since 1989 by Hamilton Medical under license from the University of Florida. *The University of Florida received royalties from a licensing agreement for a commercial transport ventilator named the Hamilton MAX*.

Gravenstein D, Beneken JEW, Lampotang S, Gravenstein N, Brooks MA, Gibby GL, Atwater RJ: Method for non-invasive, intermittent, and/or continuous hemoglobin, arterial oxygen content and hematocrit determination. US Patent 5,101,825 issued April 7, 1992

Lampotang S, Gravenstein JS, Gravenstein N, Banner MJ, Gravenstein D: CO<sub>2</sub> diagnostic monitor with rupturable container. US Patent 5,156,159 issued October 20, 1992

Gibby GL, Lampotang S, Hathiram D, Gravenstein N: System and method for in-line heating of medical fluid. US Patent 5,180,896 issued January 19, 1993

Lampotang S, Good ML, Gravenstein JS, Carovano RG: Method and apparatus for simulating neuromuscular stimulation during medical surgery. US Patent 5,391,081 issued February 21, 1995. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Gravenstein D, Gravenstein N, Melker RJ, Lampotang S, Sultan A: Transtracheal energy application and sensing system for intubation: method and apparatus. US Patent 5,560,351, issued October 1, 1996

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: Self-regulating lung for simulated medical procedures. US Patent 5,584,701 issued December 17, 1996. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

European Patent Office, 0440745, issued 1997: Method for noninvasive intermittent and/or continuous hemoglobin, arterial oxygen content, and hematocrit determination (with D

Gravenstein, G Gibby)

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: Apparatus for and method of synchronizing cardiac rhythm related events. US Patent 5,769,641, issued 1998. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: An apparatus for and method of simulating bronchial resistance or dilation. US Patent 5,772,442, issued 1998. The University of Florida continues to receive royalties from a licensing agreement toMedical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: An apparatus and method of detecting and identifying a drug. US Patent 5,772,443, issued 1998. The University of Florida continues to receive royalties from a licensing agreement toMedical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: Apparatus and method of simulating breathing sounds. US Patent 5,779,484, issued 1998. *The University of Florida continues to receive royalties from a licensing agreement toMedical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS* 

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: Apparatus and method for simulating lung sounds in a patient simulator. US Patent 5,868,579, issued 1999. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: An apparatus and method for quantifying fluid delivered to a patient simulator. US Patent 5,882,207, issued 1999. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Lampotang S, Melker RJ, Blanch PB, Rijhwani A: Gas blender. US Patent 5,887,611, issued 1999

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: Apparatus for and method of simulating the injection and volatilizing of a volatile drug. US Patent 5,890,908, issued 1999. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Lampotang S, van Meurs WL, Good ML, Gravenstein JS, Carovano RG: Apparatus and method of simulating the determination of continuous blood gases in a patient simulator. US Patent 5,941,710, issued 1999. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Melker RJ, Banner MJ, Lampotang S, Blanch PB, Euliano N, Carovano RG: Hybrid microprocessor controlled ventilator unit. US Patent 6,000,396, issued 1999

Gravenstein D, Lampotang S, Melker RJ: Plastic optical fiber airway imaging system. US Patent 6,115,523 issued 2000

Lampotang S, Gravenstein JS, van Oostrom JHM: Ventilation apparatus and anesthesia delivery system. US Patent 6,131,571 issued 2000

Lampotang S, van Oostrom JHM: Lung classification scheme: a method of lung class identification and inspiratory waveform shapes. US Patent 6,135,105 issued 2000

Gravenstein D, Gravenstein N, Melker RJ, Lampotang S, Sultan A: Transtracheal energy application and sensing system for intubation: method and apparatus. US Patent 6,161,537 issued 2000

van Meurs WL, Lampotang S, Good ML, Euliano TY, Beneken JEW, Carovano RG, Ellis MF, Azukas JB, McClure MW, de Beer NAM, Gravenstein JS: Life support simulation system simulating human physiological parameters. US Patent 6,273,728 issued August 14, 2001. The University of Florida continues to receive royalties from a licensing agreement to Medical Education Technologies, Inc., now acquired by CAE Healthcare to manufacture and sell worldwide the Human Patient Simulator (HPS) and derivatives of the HPS

Gravenstein D, Lampotang S, Melker RJ, Gabrielli A: Imaging scope. US Patent 6,322,498, issued November 27, 2001

Lampotang S, Langevin P: A method and apparatus for triggering an event at a desired point in the breathing cycle. US Patent 6,370,419, issued April 9, 2002

Lampotang S, Langevin P: A method and apparatus for coordinating an event to desired points in one or more physiological cycles. US Patent 6,597,939, issued July 22, 2003

Melker RJ, Banner MJ, Lampotang S, Blanch PB, Euliano NR, Carovano RG: Ventilatory method utilizing body length-based parameter calculations. US Patent 6,976,487 B1, issued December 20, 2005

Lampotang S, Lizdas DE, Liem EB: Interactive simulation of a pneumatic system. US Patent 7,128,578, issued October 31, 2006

Hickle RS, Lampotang S: Apparatus and method for mask free delivery of an inspired gas mixture and gas sampling. US Patent 7,152,604, issued Dec 26, 2006. This patent is part of a suite of patents protecting the intellectual property in the J&J Ethicon EndoSurgery SedaSys semi-automated propofol sedation delivery system

Melker RJ, Banner MJ, Lampotang S, Blanch PB, Euliano NR, Carovano RG: Hybrid microprocessor controlled ventilator unit. US Patent 7,156,095 B2, issued January 2, 2007

Hickle RS, Lampotang S: Smart supplies, components and capital equipment. US Patent 7,299,981, issued November 27, 2007. This patent is part of a suite of patents protecting the intellectual property in the J&J Ethicon EndoSurgery SedaSys semi-automated propofol sedation delivery system

Hickle RS, Lampotang S: Smart supplies, components and capital equipment. US Patent 7,559,483, issued July 14, 2009. This patent is part of a suite of patents protecting the intellectual property in the J&J Ethicon EndoSurgery SedaSys semi-automated propofol sedation delivery system

Lampotang S, Melker RJ, Silverman DN: Marker detection method and apparatus to monitor drug compliance. US Patent 7,820,108, issued October 26, 2010. This patent is part of a suite of patents protecting the intellectual property in the J&J Ethicon EndoSurgery SedaSys semi-automated propofol sedation delivery system

Hickle RS, Lampotang S: Apparatus and method for mask free delivery of an inspired gas mixture and gas sampling. US Patent 7,997,271, issued August 16, 2011. This patent is part of a suite of patents protecting the intellectual property in the J&J Ethicon EndoSurgery SedaSys semi-automated propofol sedation delivery system

Melker RJM, Bjoraker DG, Lampotang S: System and method for monitoring health using exhaled breath. US Patent 8,211,035, issued July 3, 2012. *The University of Florida continues to receive royalties from this licensing agreement* 

Gravenstein N, Esener D, Lampotang S, Gilmore MD: Materials and methods for maintaining proper body temperature. US Patent Number 8,544,115 issued October 1, 2013. *The University of Florida has received royaltiesfrom the Williams Sports Group for sales of the Temperature Management System (TMS) to NFL, college and high school football teams* 

Lampotang S, Lizdas DE, Tumino JJ, Gravenstein N: Display-based interactive simulation with dynamic panorama. US Patent Number 8,605,133 issued December 10, 2013

Gravenstein D, Rice M, Lampotang S, Gravenstein N, Deitte L: Methods and devices for noninvasive measurement of energy absorbers in blood. US Patent Number 8,818,472 issued August 26, 2014

Lampotang S, Gravenstein N, Lizdas DE, Luria IT, Peterson MJ: Interactive mixed reality

simulator and uses thereof. US Patent 9,251,721, issued February 2, 2016

# **Patent Applications**

Hickle RS, Lampotang S. US Patent application 20030040700. Apparatuses and methods for providing IV infusion administration. Published February 27, 2003

Hickle RS, Lampotang S, Niklewski PJ, Bishop G. US Patent application 20040107965. System and method for gas supply and delivering gas to a patient. Published June 10, 2004

Lampotang S, Gravenstein N. US Patent application 20050205098. Apparatus and method to deliver dilute O2 by nasal cannula or facemask. Published September 22, 2005

Lampotang S, Gravenstein N. US Patent Application 20060060199. Self inflating resuscitation system. Published March 23, 2006

Lampotang S, Gravenstein N. US Patent Application 20060150970. Apparatus and methods to titrate O<sub>2</sub> content delivered to open delivery systems and mitigate fire risk. Published July 13, 2006

Lampotang S, Lok B, Fishwick PA, Quarles JP. US Patent application 20100159434. Mixed Simulator and Uses Thereof. Published June 24, 2010

Lampotang S, Gravenstein N, Lizdas L, Luria I, Peterson M. Interactive mixed reality system and uses thereof. UF #-13392, Provisional patent application filed, April 2010

- Lampotang S, Gravenstein N, Lizdas L, Luria I, Peterson M: International Patent Application Docket No. UF.917XC1PCT. Interactive mixed reality system and uses thereof. UF #-13392, published October 14, 2011
- Lampotang S, Gravenstein N, Lizdas DE, Luria IT, Peterson MJ: Interactive Mixed Reality System and Uses Thereof. UF Docket # UF917XC1, filed June 7, 2012
- Filed rebuttal to USPTO First office action on UF.917XC1 (UF#13392; Interactive Mixed Reality Simulator and Uses Thereof) on November 3, 2014
  - Issuing 2/2/16 as US Patent 9,251,721

Lampotang S, Gravenstein N: Ladder catheter drainage outflow and backpressure prevention optimization system. UF #-13512, September, 2010

- PCT patent application for dependent loop management filed on 9/2/2011
- Lampotang S, Gravenstein N, Schwab WK, Lizdas DE, Enneking FK: Context-sensitive flow interrupter and drainage outflow optimization system. WO 2012/033906 A2, published March 15, 2012

Tighe PJ, Gravenstein N, Lampotang S, Boezaart A: Airway support device with integrated provision of oxygenation and ventilation. UF #13486, August 12, 2010

UF Disclosure # 13825—Integrated Consciousness and Pulse Oximeter Monitor—Gravenstein N, Lampotang S, Lizdas D, Schwab W, Luria I – June 2011

- Gravenstein N, Lampotang S, Lizdas DE, Schwab WK, Yash B: Patient in-the-loop participatory care and monitoring. UF #13825, Serial No. 61/649,165, Provisional patent filed with the US Patent Office on May 18, 2012
- UF.1044XC1PCT (UF#13825); Patient in-the-loop Participatory Care and Monitoring Gravenstein N, Lampotang, Lizdas, Bisht – PCT application filed 5/17/13 and assigned Serial No. PCT/US13/41590

UF.1095P (UF#14445); Ihnatsenka, Lampotang, Lizdas, Gravenstein D, Boezaart: Enhanced Ultrasound Imaging Interpretation and Navigation Provisional patent filed 5/17/13 and assigned Serial No. 61/824,559

UF.1220P (UF#15508); Lampotang S, Lizdas DE, Ihnatsenka B: Simulation Features Combining Mixed Reality and Modular Tracking. Provisional patent filed 1/10/15 and assigned Serial No. 62/101,997; filed as utility (non-provisional patent) on 1/11/16

Continuation Patent Application: Interactive Mixed Reality Simulator UFW-13392/SLE ref UF.917XCD1 filed on 12/28/15

# **Disclosures to UF Office of Technology Licensing**

Disclosed use of electronic nose as a peanut sniffer to prevent allergic reactions - 2/04

Disclosed Stylet with channel for removable imaging guide 3/04, patents issued

Disclosed Airway device with removable imaging guide 4/04

Display-based interactive simulation with dynamic panorama, September 4, 2009, patent issued Self-priming Bacteriocidal Intravenous Line Access Port System, 10/29/10

Applications of polyquaterniums in healthcare and daily life, UF 13731, March 3, 2011

Lampotang & Lizdas: Modular Quick Connect/Disconnect Attachment for Expensive Equipment, disclosed April 13, 2012

Lampotang, Gravenstein, Lizdas: Personalized medicine through accounting for patient variability, disclosed September 30, 2012

Lampotang, Gravenstein: Medical Equipment Infection Control, disclosed October 3, 2012

Gravenstein, Dolce, Lizdas, Lampotang: Guidance system for faster and more accurate placement of orthodontic brackets, disclosed to UF Office of Technology Licensing on June 25, 2014; UF exerted, provisional patent application being drafted

Gonsalves, Lizdas, Lampotang: In-situ, just in time apparatus and method for learning ultrasound and planning procedural approach, disclosed to UF Office of Technology Licensing on November 19, 2014, UF exerted, provisional patent application being drafted

Lampotang, Lizdas, Ihnatsenka: Enhancements to Interactive Mixed Reality Simulator and Uses Thereof, disclosed to UF Office of Technology Licensing on December 23, 2014, UF exerted, provisional patent application being drafted

#### SOFTWARE DEVELOPED AND COPYRIGHTED

# Samsun Lampotang, PhD

Thoman J, Gravenstein D, Lampotang S: Brain model, UF#9435, 1998

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 1.0. Proof of concept done with the free, trial version of Director 7.0. Basic mechanical ventilation. 1999

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 2.0. Implemented with the educational version of Director 7.02. Background, piping and general layout modified to reflect the layout of a working anesthesia machine. Basic mechanical ventilation animated. 1999

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 2.01. Added gas escaping from scavenging system positive pressure relief valve. Showed a partially expired CO2 scrubber. 1999

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 2.1. Showed CO2 absorption. Added ventilator power switch, a rough O2 flush and gas sounds. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 3.0. Added manual ventilation, tool tips and a bellows tear scenario, exhibited at STA 2000 meeting. January 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 3.1. Added tempo control. Modified bellows tear and tool tips check box. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 3.2. Animated manual ventilation bag. Modified APL valve to more closely model a real anesthesia machine. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 3.3. Improved the animation of the bellows and positive pressure relief valve. Resulting animation was smoother, faster and easier to incorporate into an interrelated system. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 3.4. O2 flush modified to more closely match a real system. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 4.0. O2 disconnect alarm sound added. A help page was created and a link to it was added. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 4.1. Bellows drive gas shown during manual ventilation. The gas scavenging system was changed to show a smoother and more consistent pressure relief and vacuum relief scenarios. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 4.2. Scavenging bag animated with mathematical manipulation instead of tweening. Isoflurane fill cap leak shown. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 4.3. Gas control knobs color-coded. Minimal compulsory 200 cc/min. O2 flow shown. Bellows drive gas valves controlled by mathematical equations instead of tweening. 2000

Lampotang S, Dobbins W: Virtual Anesthesia Machine version 5.0. Gradual onset of gas introduced into the system. Speed control modified to follow mouse movements. CO2 molecules shown during manual ventilation. May 2000

Lampotang S, Lizdas D, Liem EB: Virtual Anesthesia Machine version 5.1. Modifications to nitrous and oxygen gas supply modules: Pressure regulators added. Placement of cylinder pressure gauges and check valves modified to reflect the most common arrangement. Gas molecules stationary if the corresponding gas is not flowing. August 2000

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Lampotang S, Lizdas D, Liem EB: Virtual Anesthesia Machine version 7.0. Implemented with Director 8.0. Ventilator controls added. Gradual introduction and washout of gasses added. Differential flow rates added to reflect internal relative changes. Pictures of actual Ohmeda Modulus II anesthesia machine components added. March 2001

Lampotang S, Lizdas D, Liem EB: Virtual Fabius GS—a Web-based trainer for a new anesthesia machine design (version 1.0). Released May 21, 2001 to Drager Medical Inc. for use in educating personnel and clinicians about the Fabius GS anesthesia machine

Liem EB, Lizdas D, Lampotang S: Virtual Anesthesia Machine, version 7.1. Released June 28, 2001, Copyright 2001. Registration Number TXu991-345

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Lampotang S, Lizdas D: Virtual Anesthesia Machine version 8.34. Turkish legends added. December 2002

Lampotang S, Lizdas D: Virtual Anesthesia Machine version 8.35. Albanian and Greek legends added. March 2003

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Lampotang S, Lizdas D: Virtual Anesthesia Machine version 8.37. Georgian and Japanese legends added. Georgian and Japanese gas color codes added. June 2003

Lampotang S, Lizdas D: Virtual Anesthesia Machine version 8.38. Czech and Farsi legends added. October 2003

Lampotang S, Lizdas D, Liem EB, Gravenstein JS: The Anesthesia Patient Safety Foundation Anesthesia Machine Workbook, version 1.1 (60 pages) posted to the Virtual Anesthesia Machine web site, http://www.anest.ufl.edu/vam. April 13, 2004

Lampotang S, Lizdas D: Instructor version of VAM. May 2004. This premium version of the Virtual Anesthesia Machine simulation offers more features like spontaneous ventilation, machine faults and monitoring (physiologic and anesthesia machine) compared to the basic and free VAM simulation. The instructor VAM is only accessible via an educational coupon provided by a corporate partner as a means of making the Virtual Anesthesia Machine team self-sufficient in funding. Current corporate partners in distributing educational coupons for instructor VAM are Abbott Laboratories Japan and potentially Datex-Ohmeda

The VAM web simulation in June 2004 features legends in 19 languages (Albanian, Arabic, Chinese, Czech, Dutch, English, Farsi, French, Georgian, German, Greek, Hebrew, Italian, Japanese, Korean, Portuguese, Russian, Spanish and Turkish)

Developed proof of concept dialysis machine simulation - September 2003 - see Dialysis at <a href="http://vam.anest.ufl.edu/demos">http://vam.anest.ufl.edu/demos</a>

Developed a Physics simulation of elastic and inelastic collisions as part of UF DOCE funded work - December 2003 - see Physics at <a href="http://vam.anest.ufl.edu/demos">http://vam.anest.ufl.edu/demos</a>

Totally redesigned VAM web site with a new easier to remember URL <a href="http://vam.anest.ufl.edu">http://vam.anest.ufl.edu</a> was posted to the web on 11/1/03. The new VAM web site provides improved navigation, password access, email address authentication and greater control on who has access to what materials within the web site (tiered access) as well as vastly increasing "downstream control" to reduce the ability of users to "download once, use many". A database was implemented to manage membership and control access. The resulting VAM web site has allowed implementation and enforcement of a "One use, one hit" policy in an effort to cement the status of the UF VAM web site as the top listing upon a Google search on "anesthesia machine" in the past 2.5 years

Developed a proof of concept Conceptual Reality simulation to visualize drug interactions and inhibition - March 2004 - see Pharmacodynamics at <a href="http://vam.anest.ufl.edu/demos">http://vam.anest.ufl.edu/demos</a>

Developed techniques applicable to simulation of clinical algorithms. Users can take any one of a multitude of options available at a branching point. At any time, users can "rewind" back in time to any branch point and select a different option, especially if it becomes apparent that the initial option selected was unwise. For clinical algorithms, this algorithm simulation technique may be especially useful as it provides context, immediacy and an opportunity to practice -

S. Lampotang

August 2003, see ADI at <a href="http://vam.anest.ufl.edu/demos">http://vam.anest.ufl.edu/demos</a>

Implemented an <u>opaque "blackbox" simulation</u> of an anesthesia machine as part of a proposed study of different simulation modalities. This project encapsulated a shared simulation engine as a Reusable Learning Object that was used to drive two totally different external representations of an anesthesia machine. Based on the intrinsic principle of Learning object theory, the content (simulation engine, models and equations) was effectively separated from the format (externally visible representation) facilitating re-use - May 2004, see Opaque VAM at <a href="http://vam.anest.ufl.edu/demos">http://vam.anest.ufl.edu/demos</a>

Made video interactive, instead of passive, by integrating QuickTime video playback with a Shockwave movie in a simulation of a BBraun Diapact machine used for CVVH therapy. Users can now be required to demonstrate grasp of material previously displayed on video before video clip will resume - December 2003 - see Dialysis at <a href="http://vam.anest.ufl.edu/demos">http://vam.anest.ufl.edu/demos</a>

Registered copyright for dialysis machine simulation - 7/04

Opaque Virtual Anesthesia Machine - Certificate of Registration of Copyright No: TXu1-200-239, registered October 8, 2004

Transparent Reality Simulation of Adverse Drug Interactions and Clinical Algorithms with Branching Paths - Certificate of Registration of Copyright No: TXu1-203-018, registered October 8, 2004

Instructor Version of Virtual Anesthesia Machine simulation - Certificate of Registration of Copyright No: TXu1-029-342, registered October 8, 2004

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ChloraPrep Skin Prep Simulation for the iPad released to CareFusion, June 29, 2012

Lizdas, Gibby, Lampotang: Screen-based simulation of Operating Room Electrical Safety delivered to Gordon Gibby, MD and Mark Rice, MD for ASA 2013 panel with MOCA Safety credits, August 13, 2013

## Samsun Lampotang, PhD Materials Considered

Plaintiffs' Expert Report of Michael W. Buck

Plaintiffs' Expert Report of Yadin David

Plaintiffs' Expert Report of Said Elghobashi

Plaintiffs' Expert Report of William Jarvis

Plaintiffs' Expert Report of Dan Koenigshofer

Deposition Transcript of Troy Bergstrom

Deposition Transcript of John Rock

Deposition Transcript of Al Van Duren

Deposition Transcript of Al Van Duren

Deposition Transcript of David Westlin

Deposition Transcript of Teri Woodwick-Sides

Deposition Transcript of Karl Zgoda

Robert Crowder Deposition Transcript

Crowder Deposition Exhibit 372 (3MBH01735994)

Crowder Deposition Exhibit 373 (3MBH00024857)

Crowder Deposition Exhibit 374 (3MBH00022367)

Crowder Deposition Exhibit 375 (3MBH00026515)

Crowder Deposition Exhibit 376 (3MBH00026490)

Crowder Deposition Exhibit 377 (3MBH01929391)

Crowder Deposition Exhibit 378 (3MBH00125235)

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Crowder Deposition Exhibit 381 (3MBH01922948)

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3MBH00761310

3MBH00761311

505 Design History File (3MBH00127752-3MBH00129005)

750 Design History File (3MBH00046310-3MBH00046821)

750 Redesign History File (3MBH00046186-3MBH00046309)

3/7/2017 Order Sustaining VitaHEAT Relevance Objections

4/13/2017 Order denying Plaintiffs' objection to Mag Judge Order and Affirming 3/6/2017 Order re VitaHEAT

ASHRAE Standard 52.2 User Guide

ASHRAE Chapter 8, Health Care Facilities (2015)

ASHRAE D-90550, pages 29-30

CDC Healthcare Associated Infection Progress

# EXHIBIT DX3

TO DECLARATION OF BENJAMIN W. HULSE IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SAMSUN LAMPOTANG, PH.D.

# Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment

A. T. Bernards, PhD; H. I. J. Harinck, PhD; L. Dijkshoorn, PhD; T. J. K. van der Reijden, Ing; P. J. van den Broek, PhD

#### ABSTRACT

Two outbreaks of multidrug-resistant Acinetobacter baumannii occurred in our hospital. The outbreak strains were eventually isolated from respiratory ventilators, an apparatus used to cool or warm patients, and four continuous veno-venous hemofiltration machines. Removing dust from the machines and replacing all dust filters brought the outbreaks to an end (Infect Control Hosp Epidemiol 2004;25:1002:1004).

Multidrug-resistant Acinetobacter baumannii continues to cause outbreaks in intensive care units (ICUs) around the world. <sup>13</sup> The epidemiology of A. baumannii is diverse. Outbreaks may originate from a single contaminated source such as ventilators or room humidifiers, the outbreak strain may become widespread with heavy contamination of the environment, or no reservoir may be found. <sup>15</sup>

Between October 2000 and July 2003, two outbreaks caused by two distinct strains of multidrug-resistant *A. baumannii* occurred in our university hospital. Both outbreaks occurred in the medical ICU and spread to other ICUs located in different parts of the hospital.

The first outbreak began in October 2000 and was caused by a multidrug-resistant strain of A. baumannii. In total, 29 patients were affected, 27 being colonized and 2 having a possible infection (positive blood cultures). All 29 patients were colonized in the respiratory tract. In 17 patients, the respiratory tract was the body site found to be colonized first. Colonized patients were placed in strict isolation (ie, placed in a separate room with an anteroom with negative air pressure). In addition, healthcare workers entering the patients' rooms wore protective clothing, gloves, and a mask at all times. Hygienic measures were intensified (ie, healthcare workers were instructed about strict adherence to hand hygiene between and during bronchial washings, flushing gastric tubes, caring for wounds, and washing of patients). Supplies of utility goods at the patients' bedsides were kept to a minimum. The cleaning of reusable items such as ventilation bags and tubing was improved by placing them appropriately in the washing machine. Hammocks for weighing patients were adequately cleaned and disinfected. Also, the ward was cleaned more frequently, with particular attention paid to areas where dust was likely to gather.

Although environmental cultures showed no contamination of objects on the ward, the medical ICU was at one time closed and cleaned extensively. However, soon after the ward was reopened, the outbreak strain was again isolated from patients. A second investigation into a possible environmental source was begun.

The second outbreak of a multidrug-resistant strain of A. baumannii began in May 2003 in the medical ICU.

One patient had an infection of a hip prosthesis by *A. baumannii* superimposed on an infection caused by *Staphylococcus aureus*. Three other patients became colorized with the multidrug-resistant strain, two in the respiratory tract and one in the digestive tract. When a patient in the neurosurgery ICU who had not been admitted to the medical ICU became colonized with the same strain in an abdominal wound, an investigation was started. The findings of the investigation of the first outbreak were helpful in tracing the source of the second outbreak quickly.

#### METHODS

Initially during the first outbreak, 110 environmental objects were sampled including sinks, table tops, computer keyboards, objects on the crash car, ventilation masks, key panels of ventilators, monitors, infusion equipment, hammocks for weighing patients, air conditioner inlets and outlets, and dust. Medical equipment was sampled after it had been cleaned and disinfected according to standard procedures.

Later during the first outbreak, the environmental investigation consisted of sampling a so-called test lung used to check the ventilators before each new patient, a ventilator that was cleaned and disinfected according to standard protocol, and the filters inside the Bair Hugger (Augustine Medical, Inc., Eden Prairie, MN). The ventilator was sampled by opening both the pneumatic and the electronic parts and harvesting the dust from the interior. The interior of the ventilation tubing inside the pneumatic part of the ventilator was not sampled. The Bair Hugger is connected to the patient's mattress by a tube through which cold or warm air is passed to either cool or warm the patient. Several dust filters from the interior of the Bair Hugger were cultured.

Samples for cultures were collected from the surface of the objects with a moistened swab. Dust was collected using moistened swabs. Swabs were then vigorously shaken in 40 mL of acetate mineral medium for enrichment. Filters were cut into small pieces and added to the mineral medium. After 48 hours in a shaking incubator at 30°C, the medium was subcultured onto sheep blood agar and cystine lactose electrolyte deficient agar. Sheep blood sedimentation plates were placed in patients' isolation rooms, on the ward, and in the nurses' station.

Isolates were identified as *Acinetobacter* and susceptibility tests were performed using VITEK 2 (bioMérieux, Hertogenbosch, the Netherlands). Species and strain identification was performed using amplified fragment-length polymorphism (AFLP).

AFLP, previously found to be a useful fingerprinting method, <sup>7</sup> was performed according to Nemec et al. <sup>8</sup> Briefly, purified DNA was digested with *Eco*Rl and *Mse*I while ligation of *Eco*Rl and *Mse*I adapters was performed. Polymerase chain reaction was performed with a Cy5-labeled *Eco*RI+A primer and a *Mse*I+C primer (A and C representing selective nucleotides). The ALFexpress II DNA analysis system (Amersham Biosciences, Roosendaal, the Netherlands) was used for fragment sep-



aration. Fragments of 50 to 500 bp were subjected to cluster analysis using BioNumerics software (release 2.5; Applied Maths, Sint-Martens-Latem, Belgium) with an overall tolerance setting of 0.1%. The Pearson product moment coefficient (r) was used as a measure of similarity, and the unweighted pair group average linked method was used for grouping.

#### RESULTS

The initial environmental investigation revealed no contaminated objects. Only one sedimentation plate from a colonized patient's isolation room within 3 m of the patient's bed was positive. During the subsequent environmental investigation of the first outbreak, the outbreak strain was isolated from medical equipment (ie, from dust in the interior of a mechanical ventilator and from filters inside the Bair Hugger). The isolates of the patients and the isolates from the ventilator and the Bair Hugger were resistant to all beta-lactam antibiotics, cotrimoxazole, and the fluoroquinolones. They were intermediately susceptible to meropenem and amikacin, and fully susceptible to tobramycin only. The multidrug-resistant Acinetobacter was identified as A. baumannii by AFLP because the isolates clustered with the reference strain of A. baumannii 50% or more. The AFLP profiles of patient and environmental isolates clustered well above 90%, indicating that they belonged to the same strain (Figure). After removal of the dust from the interior of the ventilator by forced air, the outbreak strain was no longer isolated from the machine.

The second outbreak was caused by an *Acinetobacter* resistant to all beta-lactam agents tested, the fluoroquinolones, and the aminoglycosides. The isolate was susceptible to meropenem only.

Different ventilators had been used for the affected patients. The only pieces of equipment that had been used by all colonized patients except one were the continuous veno-venous hemofiltration (CVVH) machines. During the 2-month period from the day of admission of the index patient to the day the CVVH machines were sampled, 175 patients were admitted to the medical ICU and the neurosurgery ICU. Eleven of these 175 patients received CVVH. The outbreak strain was isolated from 3 (27%) of the 11 patients, and 2 (1%) of 164 patients not receiving CVVH were found to harbor the outbreak strain. Thus, patients who had the outbreak strain were more likely to have received CVVH (odds ratio, 30.4; 95% confidence interval, 6 to 146). The outbreak strain was isolated from dust inside both the blood compartment and the substitution compartment of 4 of the 6 machines present in our hospital. The isolates of both patients and CVVH machines were identified as A. baumannii and appeared to represent the same strain on AFLP analysis (Figure). After removal of the dust from the interior of all CVVH machines, the outbreak strain was no longer isolated from any of the machines or patients.

#### DISCUSSION

Bacteria belonging to the genus Acinetobacter are known to be capable of surviving in dry conditions.  $^{9.10}$ 

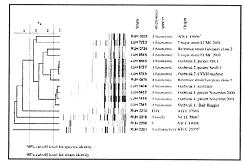


FIGURE. Amplified fragment-length polymorphism fingerprints of patients' isolates, of isolates from medical equipment of the first outbreak (outbreak 1) and the second outbreak (outbreak 2), and of reference strains of five Acinetobacter species, including A. baumannii. Levels of similarity are expressed as percentages of similarity. RUH = Rotterdam University Hospital; LUHC = Leiden University Hospital; LUHC = Leiden University Medical Center; MICU = medical intensive care unit; NeulCU = neurosurgery ICU; CVVH = continuous veno-venous hemofilitration; ATCC = American Type Culture Collection; NCTC = National Collection of Type Culture

Dust contaminated with *A. baumannii* may thus be a relevant vehicle in the transmission of this bacterium.

In our 882-bed, tertiary-care hospital, *A. baumannii* is not a frequent occurrence. The numbers of patients from whom *A. baumannii* was isolated from 1999 through 2002 were 5, 23, 29, and 5, respectively, with incidences of 0.03, 0.07, 0.06, and 0.03 per 1,000 patient-days, respectively. Ten of the 23 *A. baumannii* isolates in 2000 and 19 of the 29 in 2001 were the outbreak strain and occurred in the ICUs only.

In the first outbreak, the strain involved was found in the interior of a ventilator and of the Bair Hugger. After removal of the dust inside all ventilators and replacement of the filters of the Bair Hugger, the outbreak strain was no longer isolated from patients. In the second outbreak, the strain involved was isolated from dust inside the CVVH machines, which had been used on all colonized patients except one. After removal of the dust from the CVVH machines using forced air, the outbreak strain was no longer isolated.

During operation, a fan provides continuous airflow through ventilators and CVVH machines to cool the circuit boards. It is possible that dust carrying bacteria is passed in and out of the machines on this air current, despite dust filters being placed at the air inlets and outlets. The Bair Hugger is designed to create an airflow; dust is sucked into the machine, with filters becoming contaminated and possibly serving as a secondary source of transmission. It was not known how long the filters had been in place, and there was no protocol for regular replacement of the filters. We believe the outbreak strain was transmitted by being carried on contaminated dust from within the machines to the exterior during operation when a fan created an air current. Thus, the exterior of

the machines may have been contaminated and become a secondary source of spread.

We found contaminated dust in the interior of different types of machines used by patients on two different occasions. After this dust was removed, no further cases were observed. Hence, dust may be relevant in the epidemiology of A. baumannii or of any microorganism capable of surviving under dry conditions. We recommend that during outbreaks of A. baumannii the removal of dust from the interior of machines that patients come in close contact with be an integral part of cleaning and disinfection procedures.

Dr. Bernards is from the Department of Medical Microbiology, Dr. Harinck is from the Intensive Care Center, and Drs. Dijkshoorn and van den Broek and Ms. van der Reijden are from the Department of Infectious Diseases, Leiden University Medical Center, Leiden, the Netherlands.

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## Epidemiologic Study of Nosocomial Urinary Tract Infections in Saudi Military Hospitals

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#### ABSTRACT

A case-control study of patients with and without confirmed UTI was performed to identify risk factors for nosocomial UTI. Duration of hospitalization, unit of admission, history of diabetes mellitus or debilitating diseases, and duration and number of urinary catheters were independently associated with increased risk of nosocomial UTIs (Infect Control Hosp Epidemiol 2004;25:1004-1007).

In developing countries, nosocomial infection is increasingly being recognized as a significant problem. Nosocomial infection often results in extended hospitalization, expensive therapy, and morbidity and mortality.1,2 Up to 10% of all hospitalized patients develop nosocomial infection.3,4 Urinary tract infections (UTIs) are the most common type of nosocomial infection, accounting for 40% of all infections in hospitals and 34% of all infections in nursing homes.5.6 In hospitals, 80% to 90% of nosocomial UTIs are associated with the use of urinary catheters and an additional 5% to 10% are associated with other genitourinary manipulations.<sup>6-8</sup> Prevention and management of such infections require an intimate knowledge of their epidemiology, including risk factors.<sup>9,10</sup> Hospital infection control programs can prevent 33% of nosocomial infections, including nosocomial UTIs.11 The aims of this study were to estimate the overall rates of nosocomial infections and nosocomial UTIs and their linear trends during 5 years (1998 to 2002) and to identify potential risk factors of hospitalized patients who developed nosocomial UTIs.

To fulfill the objectives of this study, two methodologies were adopted: a case-control study of risk factors and a record review to calculate nosocomial UTI rates.

The case-control study of risk factors was performed between August 1, 2001, and July 31, 2003, at Al-Hada (400 beds), Al-Rehab (100 beds), and Prince Sultan (50 beds) military hospitals. These three hospitals are administered by the Medical Service Department of the Saudi Arabian Ministry of Defense and Aviation. All patients admitted to these hospitals for at least 72 hours during the study period were considered eligible for inclusion in the study. Among these, patients proved to have UTI were considered case-patients. The diagnosis of UTI was made according to criteria of the Centers for Disease Control and Prevention. 12 After exclusion of patients who did not fulfill eligibility criteria, three control-patients were enrolled for each case-patient through a systematic random sampling procedure using the patient admission record list (every three patients).

For all participants (case-patients and controlpatients), the following were recorded: age, gender, unit of admission, presence of a catheter, duration of catheterization, number of catheters, history of diabetes mellitus. history of immunosuppressive drug use, history of debilitating diseases (cancer, liver failure, or uremia), and duration of hospitalization. These data were collected from the patients' records during their hospital stay by a trained nosocomial infection surveillance team from the Preventive Medicine Department.

Hospital records, providing the number of patients hospitalized each month and the numbers of nosocomial infections (crude and site specific) each month, were reviewed. The overall annual rates of nosocomial infections and nosocomial UTIs during the period 1998 to 2002 were calculated by dividing the total number of nosocomial infections (crude and UTIs) pooled throughout all

# **EXHIBIT DX4**

TO DECLARATION OF BENJAMIN W. HULSE IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SAMSUN LAMPOTANG, PH.D.

0:15-md-02666-JNE-DTS Doc. 912-1 Filed 10/03/17 Page 226 Natural Rubber Latex



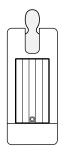








# **Warming Blankets**



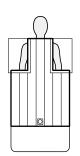
Outpatient Blanket

Cat. No. 11000/11101 84 × 36 in (213 × 91 cm)



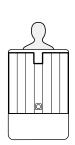
Full Body

Cat. No. 30000 84 × 36 in (213 × 91 cm)



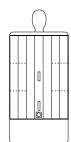
Chest Access

Cat. No. 30500 72 × 36 in (183 × 91 cm)



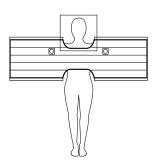
# Pediatric Full Body

Cat. No. 31000 60 × 36 in (152 × 91 cm)



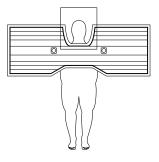
# Multi-Access

Cat. No. 31500 84 × 36 in (213 × 91 cm)



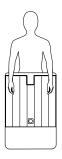
# Upper Body

Cat. No. 52200 76 × 24 in (192 × 61 cm)



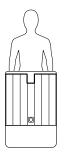
# XL Upper Body

Cat. No. 52301 84 × 36 in (213 × 91 cm)



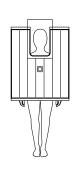
## Lower Body

Cat. No. 52500 60 × 36 in (152 × 91 cm)



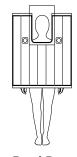
# Small Lower Body

Cat. No. 53700 35 × 24 in (89 × 61 cm)



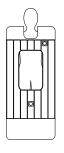
# Torso

Cat. No. 54000 42 × 36 in (107 × 91 cm)



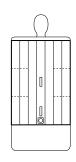
## Dual Port Torso

Cat. No. 54200 42 × 36 in (107 × 91 cm)



# Surgical Access

Cat. No. 57000 84 × 36 in (213 × 91 cm)



# Full Body Surgical

Cat. No. 61000 72 × 36 in (183 × 91 cm)



Internal Use

# 0:15 min 97 ROCTIVENS FOR 195E 912-1 Filed 10/03/17 Page 227

#### Indications for Use

The 3M™ Bair Hugger™ Temperature Management System is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric patients.

- NOT STERILE.
- Federal law (USA) restricts this device to sale by or on order of a licensed healthcare professional.

#### Contraindications, Warnings and Cautions

#### **Explanation of Signal Word Consequences**



#### WARNING:

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.



#### CAUTION:

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

## ↑ CONTRAINDICATION: To reduce the risk of thermal injury:

· Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.



#### WARNING: To reduce the risk of thermal injury:

- Do not treat patients with the Bair Hugger warming unit hose alone. Always attach the hose to a Bair Hugger warming blanket before providing warming therapy.
- Do not allow the patient to lie on the warming
- Do not allow the warming unit hose to directly contact the patient's skin during warming therapy.
- · Do not leave neonates, infants, children and other vulnerable patient populations unattended during warming therapy.
- Do not leave patients with poor perfusion unmonitored during prolonged warming therapy.
- Do not place the non-perforated side of the warming blanket on the patient. Always place the perforated side (with the small holes) directly on top of the patient in contact with the patient's skin.
- In the operating room, do not use this warming blanket with any device other than a Bair Hugger 500 or 700 series warming unit.
- Do not use a Bair Hugger 200 series warming unit in the operating room.
- Do not use a Bair Hugger 800 series patient adjustable warming unit with any Bair Hugger warming blanket.
- Do not continue warming therapy if the red Over-temp indicator light illuminates and the alarm sounds. Unplug the warming unit and contact a qualified service technician.
- Do not place patient securement device (i.e. safety strap or tape) over the warming blanket.
- Do not place the warming blanket directly over a dispersive electrode pad.



#### WARNING: To reduce the risk of patient injury or death due to altered drug delivery:

 Do not use a warming blanket over transdermal medication patches



### WARNING. To reduce the risk of injury due to interference with ventilation:

 Do not allow the warming blanket or head drape to cover the patient's head or airway when the patient is not mechanically ventilated.

#### MARNING: To reduce the potential for injury due to patient falls:

• Do not use a warming blanket to transfer or move the patient.

### CAUTION: To reduce the risk of cross-contamination:

This warming blanket is not sterile and is intended for single patient use ONLY. Placing a sheet between the warming blanket and the patient does not prevent contamination of the product.

## CAUTION: To reduce the risk of fire:

 This product is classified as Class I Normal Flammability as defined by the Consumer product Safety Commission's flammable fabric regulation, 16 CFR 1610. Follow standard safety protocols when using high intensity heat sources.



# CAUTION: To reduce the risk of thermal injury:

· Do not use if primary packaging has been previously opened or is damaged.

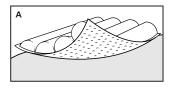


#### CAUTION: To reduce the risk of thermal injury, hyperthermia or hypothermia:

- · 3M recommends continuously monitoring core temperature. In the absence of continuous monitoring, monitor the temperature of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- Monitor cutaneous responses of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- Adjust air temperature or discontinue therapy when the therapeutic goal is reached, if elevated temperatures are recorded or if there is an adverse cutaneous response in the warmed area.

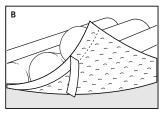
#### Instructions

Place the perforated side of the 3M™ Bair Hugger™ warming blanket (the side with small holes) directly on top of the patient in contact with the patient's skin (Figure A).

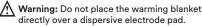


Where applicable, remove the backing from the adhesive tape strip and adhere the warming blanket to the patient (Figure B). This prevents air from flowing toward the surgical site.

> Optional: Place one cloth blanket or sheet on top of the warming blanket to increase effectiveness.



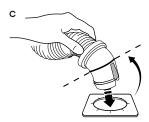
#### / Warning: Do not place patient securement device (i.e. safety strap or tape) over the warming blanket.



Insert the end of the Bair Hugger warming unit hose in the hose port (Figure C). Use a twisting motion to ensure a snug fit. A visual marker is located around the mid-section of the hose end to guide the depth of hose insertion. Support hose to ensure secure attachment.

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warming unit hose alone. Always attach the hose to a Bair Hugger warming blanket before providing warming therapy.



#### NOTE: See special considerations for Bair Hugger blankets shown below.

Select the desired temperature setting on the warming unit to initiate warming therapy. (See the Operator's Manual for your specific warming unit model)



### Caution: Patient

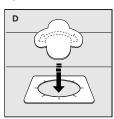
## Monitoring Recommendations:

- 3M recommends continuously monitoring core temperature. In the absence of continuous monitoring, monitor the temperature of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- Monitor cutaneous responses of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- · Adjust air temperature or discontinue therapy when the therapeutic goal is reached, if elevated temperatures are recorded or if there is an adverse cutaneous response in the warmed area.
- 5. Based on the warming unit model utilized, turn the unit off or to standby mode to discontinue warming therapy. Disconnect the warming unit hose from the warming blanket and discard the blanket per hospital policy.

#### **Special Considerations:**

#### Dual Port for Model 52200/52301 Upper Body Blankets, 54200 Dual Port Torso Blanket and 57000 Surgical Access Blanket

Two hose ports are provided for clinician preference. Place the removable hose port card in the hose port that is not being used during warming therapy (Figure D).

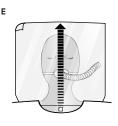


#### Head Drape for Models 52200/52301 Upper Body Blankets, 54000/54200 Torso Blankets and 57000 Surgical Access Blanket

If the patient is intubated and ventilated, lay the head drape over the patient's head and neck (Figure E); otherwise, tuck the drape between the channels of the warming blanket, away from the patient's head.

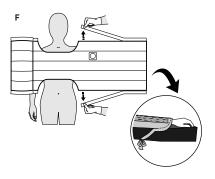
# blanket or head drape to cover the patient's head or airway when the patient is not

mechanically ventilated.



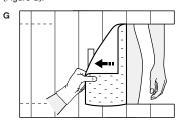
#### Models 52200/52301 Upper Body Blankets (Optional)

Pull the tie-strip tabs, centered along the upper and lower edges of the warming blanket. Tie these strips to prevent the inflated blanket from lifting away from the patient. To use the upper body blanket with one armboard, one half of the warming blanket can be tied off by wrapping tape around it or by tucking it beneath the patient (Figure F).



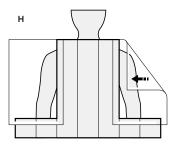
#### Model 31500 Multi-Access Postoperative and 61000 Full Body Surgical Blankets

To use the access panels, tear the uncut tab at the edge of the warming blanket. Remove the backing from the tape strip on the center of the blanket. Fold the access panel back and press against the exposed tape. Pull the panel away from the tape to release (Figure G).



#### Chest drapes for Model 30500 Chest Access Blanket

Raise the clear plastic drape to provide patient care to the upper body area (Figure H).



# ® MODE D'EMPLOI

#### Indications

Le système de gestion de la température 3M™ Bair Hugger™ est destiné à prévenir et à traiter l'hypothermie. Par ailleurs, le système de gestion de la température peut être utilisé pour assurer un confort thermique aux patients lorsque les conditions environnantes peuvent entraîner une sensation de chaleur ou de froid chez le patient. Le système de

gestion de la température convient aux adultes et aux enfants.

- NON STÉRILE.
- La loi fédérale américaine exige que ce dispositif soit commercialisé par un professionnel de santé accrédité ou sur ordonnance de celui-ci.

#### en garde de contamination croisée :

#### Explication des conséquences correspondant aux mentions d'avertissement



#### AVERTISSEMENT:

Indique une situation dangereuse qui, si elle n'est pas évitée, peut entraîner la mort ou des blessures graves.



#### MISE EN GARDE:

Indique une situation dangereuse qui, si elle n'est pas évitée, peut entraîner des blessures légères ou modérées.



#### CONTRE-INDICATION : Afin de réduire le risque de brûlures :

N'appliquez pas de chaleur sur les membres inférieurs lors du clampage de l'aorte. L'application de chaleur au niveau des membres ischémiques peut provoquer des brûlures.

#### AVERTISSEMENT : Afin de réduire le risque de brûlures :

- ne réchauffez pas les patients à l'aide du tuyau de l'unité de gestion de la température Bair Hugger. Fixez toujours le tuyau à une couverture de réchauffement Bair Hugger avant de commencer le réchauffement.
- Ne laissez pas le patient s'allonger sur le tuvau de l'unité de réchauffement.
- Ne laissez pas le tuyau de l'unité de réchauffement entrer en contact avec la peau du patient lors du réchauffement.
- Ne laissez pas les nouveau-nés, les nourrissons, les enfants et d'autres patients vulnérables sans surveillance lors du réchauffement.
- Pendant un réchauffement prolongé, ne laissez pas sans surveillance les patients présentant une mauvaise perfusion.
- Ne placez pas le côté non perforé du matelas de réchauffement contre le patient, Placez toujours le côté perforé (avec les petits trous) directement sur la peau du patient.
- Dans la salle d'opération, n'utilisez pas cette couverture de réchauffement avec un dispositif autre que l'appareil de réchauffement Bair Hugger de la gamme 500 ou 700.
- N'utilisez pas d'appareil de réchauffement Bair Hugger de la gamme 200 dans la salle d'opération.
- N'utilisez l'unité de réchauffement réglable Bair Hugger de la gamme 800 avec aucune couverture de réchauffement Bair Hugger.
- Ne poursuivez pas le réchauffement si le témoin de surchauffe rouge s'allume et que l'alarme retentit. Débranchez l'appareil de réchauffement et contactez un technicien de maintenance qualifié.
- Ne placez pas le dispositif de fixation destiné au patient (c'est-à-dire, sangle de sécurité ou ruban adhésif) sur la couverture de réchauffement.
- ne placez pas la couverture de réchauffement directement sur une électrode de dispersion.

#### AVERTISSEMENT : Afin de réduire le risque de blessures ou de décès du patient découlant d'une posologie modifiée :

 N'utilisez pas de couverture de réchauffement sur des patchs médicamenteux transdermiques.

#### AVERTISSEMENT : Afin de réduire le risque de blessures découlant d'une interférence avec la ventilation :

• Ne laissez pas la couverture de réchauffement ou le couvre-tête recouvrir la tête ou les voies respiratoires du patient lorsque ce dernier n'est pas ventilé de façon mécanique.



#### **AVERTISSEMENT:** Afin de réduire le risque de blessures découlant d'une chute du patient:

N'utilisez pas un matelas de réchauffement pour transférer ou déplacer le patient.

Cette couverture de réchauffement n'est pas stérile et doit être utilisée EXCLUSIVEMENT sur un seul patient. L'insertion d'un drap entre le matelas de réchauffement et le patient n'empêche pas la contamination du produit.

#### MISE EN GARDE : Afin de réduire le risque d'incendies:

 Ce produit est répertorié dans la catégorie de matériau I (normalement inflammable), tel que défini par la norme d'inflammabilité des vêtements textiles de la Consumer Product Safety Commission, article 16 CFR, partie 1610. Respectez toujours des protocoles de sécurité standard lorsque vous utilisez des sources de chaleur à haute intensité.

#### MISE EN GARDE : Afin de réduire le risque de brûlures:

• N'utilisez pas le produit si l'emballage est ouvert ou endommagé.

#### MISE EN GARDE : Afin de réduire le risque de brûlures, d'hyperthermie ou d'hypothermie:

- 3M recommande une surveillance continue de la température centrale. En l'absence d'une surveillance continue, contrôlez la température des patients qui ne sont pas en mesure de réagir ni de communiquer et/ou qui sont insensibles à la température. Effectuez cette vérification toutes les 15 minutes ou selon le protocole de l'établissement.
- Contrôlez les réactions cutanées des patients qui ne sont pas en mesure de réagir ni de communiquer et/ou qui sont insensibles à la température. Effectuez cette vérification toutes les 15 minutes ou selon le protocole de l'établissement.
- Réglez la température de l'air ou interrompez le traitement lorsque les objectifs thérapeutiques ont été atteints, lorsque des températures élevées sont enregistrées ou lorsque le patient présente une réaction cutanée indésirable.

#### Instructions

- Placez le côté perforé de la couverture de réchauffement Bair Hugger™ 3M™ (le côté comportant de petits trous) directement sur la peau du patient (Figure A).
- Le cas échéant, retirez le film de protection de la bande adhésive et collez la couverture de réchauffement sur le patient (Figure B). Cette opération empêche l'air de se déplacer vers le site opératoire.

Facultatif: posez un drap sur la couverture de réchauffement pour accroître son efficacité.



Avertissement : ne placez pas le dispositif de fixation destiné au patient (c'est-à-dire, sangle de sécurité ou ruban adhésif) sur la couverture de réchauffement.

Avertissement : ne placez pas la couverture de réchauffement directement sur une électrode de dispersion.

Insérez l'extrémité du tuyau de l'unité de réchauffement Bair Hugger dans l'orifice de branchement (Figure C). Exercez un mouvement de torsion pour assurer un bon ajustement. Un repère visuel est situé au milieu de l'extrémité du tuyau pour guider la profondeur d'insertion Maintenez le tuyau afin d'assurer une fixation adéquate.



Avertissement : Ne réchauffez pas le patient directement à l'aide du tuyau de l'unité de gestion de la température. Fixez toujours le tuyau à une couverture de réchauffement Bair Hugger avant de commencer le réchauffement.

#### **REMARQUE:** consultez les observations particulières des couvertures de réchauffement Bair Hugger mentionnées ci-dessous.

Pour démarrer le réchauffement, sélectionnez le réglage de la température souhaité sur l'unité de réchauffement (référez-vous au manuel de l'utilisateur pour connaître les spécifications propres à votre modèle d'appareil de réchauffement).



Mise en garde : Recommandations relatives à la surveillance du patient :

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continue de la température centrale. En l'absence d'une surveillance continue. contrôlez la température des patients qui ne sont pas en mesure de réagir ni de communiquer et/ou qui sont insensibles à la température. Effectuez cette vérification toutes les 15 minutes ou selon le protocole de l'établissement.

- Contrôlez les réactions cutanées des patients qui ne sont pas en mesure de réagir ni de communiquer et/ou qui sont insensibles à la température. Effectuez cette vérification toutes les 15 minutes ou selon le protocole de l'établissement.
- Réglez la température de l'air ou interrompez le traitement lorsque les objectifs thérapeutiques ont été atteints, lorsque des températures élevées sont enregistrées ou lorsque le patient présente une réaction cutanée indésirable.
- Sur la base du modèle d'appareil de 5. réchauffement utilisé, éteignez l'unité ou activez le mode Veille pour interrompre le réchauffement. Débranchez le tuyau de l'unité de réchauffement de la couverture et éliminez la couverture conformément au protocole de l'hônital.

#### Observations particulières:

Double entrée destinée aux couvertures pour thorax, modèle 54200, aux couvertures pour la partie supérieure du corps, modèles 52200/52301, et aux couvertures fenêtrées, modèle 57000

Deux orifices de branchement fournis, en fonction de l'installation chirurgicale. Placez la partie amovible dans l'orifice de branchement qui n'est pas utilisé lors de le réchauffement (Figure D).

Couvre-tête destiné aux couvertures pour thorax, modèles 54000/54200, aux couvertures pour la partie supérieure du corps, modèles 52200/52301, et aux couvertures fenêtrées, modèle 57000

couvre-tête sur la tête et le cou du patient (Figure E). Dans le cas contraire, glissez le drap entre les canaux de la couverture de réchauffement, éloigné de la tête du patient.



Avertissement: ne laissez pas la couverture de réchauffement ou le couvre-tête recouvrir la tête ou les voies respiratoires du patient lorsque ce dernier n'est pas ventilé de façon mécanique.

#### Couvertures pour la partie supérieure du corps, modèles 52200/52301 (facultatives)

Tirez les languettes situées le long des côtés inférieur et supérieur de la couverture de réchauffement. Fixez ces languettes pour empêcher la couverture gonflée de s'éloigner du patient. Pour utiliser la couverture pour la partie supérieure du corps avec un accoudoir, une partie de la couverture de réchauffement peut y être attachée à l'aide d'un ruban adhésif ou être glissée sous le patient (Figure F).

#### Couvertures intégrales à accès multiples, modèle 61000, et couvertures postopératoires à accès multiples, modèle 31500

Afin d'utiliser les fenêtres d'accès, déchirez la languette non coupée située sur le bord de la couverture de réchauffement. Retirez le film de protection de la bande adhésive au centre de la couverture. Repliez la fenêtre d'accès et appliquez-la contre le ruban adhésif exposé. Retirez la fenêtre du ruban adhésif (Figure G).

#### Couvertures intégrale à accès thoracique, modèle 30500

Soulevez le champ en plastique transparent pour accéder aux membres supérieurs du patient (Figure H).

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## **©E GEBRAUCHSANWEISUNG**

#### Indikationen für den Gebrauch

Das 3M™ Bair Hugger™-Temperaturmanagementsystem dient zur Vorbeugung und Behandlung einer Hypothermie. Wenn Bedingungen vorliegen, unter denen dem Patienten zu warm oder zu kalt sein könnte, kann das Temperaturmanagementsystem auch für den thermischen Komfort des Patienten genutzt werden. Das Temperaturmanagementsystem kann bei Erwachsenen und Kindern eingesetzt werden.

- Laut US-Bundesgesetz darf dieses Produkt nur an Ärzte bzw. auf ärztliche Anordnung hin verkauft werden.

#### Gegenanzeigen, Warnhinweise und Vorsichtsmaßnahmen

#### Erklärung zur Bedeutung der Signalwörter



#### WARNUNG:

Weist auf eine Gefahrensituation hin, die bei Nichtbeachtung zum Tod oder zu schweren Verletzungen führen kann.



### VORSICHT:

Weist auf eine Gefahrensituation hin, die bei Nichtbeachtung zu leichter oder mittelschwerer Verletzung führen kann.



#### GEGENANZEIGEN: Maßnahmen zur Reduzierung des Risikos thermischer Schäden:

 Führen Sie während des Einsatzes einer Aorten-Kreuzklemme keine Wärmebehandlung an den unteren Extremitäten durch. Bei einer Wärmebehandlung von ischämischen Gliedmaßen kann es zu thermischen Schäden kommen.



#### 🗸 WARNUNG: Maßnahmen zur Reduzierung des Risikos thermischer Schäden:

• Führen Sie die Behandlung von Patienten nicht durch, indem Sie nur den Schlauch der Bair Hugger-Wärmeeinheit verwenden. Schließen Sie den Schlauch stets vor der Wärmetherapie an die Bair Hugger-Wärmedecke an.

- Der Patient darf nicht auf dem Schlauch der Wärmeeinheit liegen.
- Der Schlauch der Wärmeeinheit darf während der Wärmetherapie keinen direkten Kontakt mit der Haut des Patienten haben.
- Lassen Sie Neugeborene, Kleinkinder, Kinder und andere gefährdete Patientengruppen während der Wärmetherapie nicht unbeaufsichtigt.
- Lassen Sie Patienten mit schlechter Durchblutung während einer längeren Wärmetherapie nicht unbeobachtet.
- Legen Sie die nicht perforierte Seite der Wärmedecke nicht auf den Patienten. Stets die perforierte Seite (mit den kleinen Öffnungen) direkt auf die Haut des Patienten legen.
- Verwenden Sie diese Wärmedecke im Operationssaal ausschließlich mit einer Bair Hugger-Wärmeeinheit der Serie 500 oder 700.
- Bair Hugger-Wärmeeinheiten der Serie 200 dürfen nicht im Operationssaal verwendet werden.
- Ein vom Patienten regelbares Wärmegerät der Serie Bair Hugger 800 nicht zusammen mit einer Bair Hugger-Wärmedecke verwenden.
- Unterbrechen Sie die Wärmetherapie. wenn die rote Übertemperatur-Anzeige leuchtet und das Warnsignal ertönt. Trennen Sie die Wärmeeinheit von der Stromversorgung und wenden Sie sich an qualifiziertes Fachpersonal.
- Platzieren Sie keine Vorrichtungen zur Absicherung des Patienten (d. h. Sicherungsband oder Klebestreifen) über der Wärmedecke.
- Legen Sie die Wärmedecke nicht direkt über ein Neutralelektroden-Pad.

/ WARNUNG: Maßnahmen zur Reduzierung des Risikos von Verletzungen oder Lebensgefahr für Patienten aufgrund geänderter Medikamentengabe:

Verwenden Sie keine Wärmedecken über transdermalen Medikamentenpflastern.

### 0:15 makou26.66 milhten DrTS Reduzierung des Verletzungsrisikos durch Beeinträchtigung der Beatmung:

Die Wärmedecke oder die Kopfabdeckung darf den Kopf oder die Atemwege des Patienten nicht verdecken, wenn dieser nicht mechanisch beatmet wird.

### \ WARNUNG: Maßnahmen zur Reduzierung des Verletzungsrisikos durch Stürze von Patienten:

Wärmedecken nicht zum Transportieren oder Bewegen des Patienten einsetzen.

NORSICHT: Maßnahmen zur Reduzierung des Risikos der Kreuzkontamination:

 Diese Wärmedecke ist nicht steril und NUR für eine einmalige Verwendung vorgesehen. Eine Kontamination des Produkts lässt sich auch dann nicht verhindern, wenn ein Tuch zwischen die Wärmedecke und den Patienten gelegt wird.

### VORSICHT: Maßnahmen zur Reduzierung des Brandrisikos:

 Dieses Produkt ist nach der US-Vorschrift 16 CFR 1610 für entflammbare Stoffe der Kommission für die Sicherheit von Verbrauchsgütern als Klasse I normalentflammbar klassifiziert. Bei der Verwendung von starken Wärmequellen die vor Ort gültigen Vorgaben beachten.

#### VORSICHT: Maßnahmen zur Reduzierung des Risikos thermischer Schäden:

 Nicht verwenden, wenn die Primärverpackung bereits geöffnet wurde oder beschädigt ist.

#### NORSICHT: Maßnahmen zur Reduzierung des Risikos von thermischen Schäden, Hyperthermie und Hypothermie:

- 3M empfiehlt, die Körperkerntemperatur kontinuierlich zu überwachen. Bei fehlender kontinuierlicher Überwachung die Temperatur von Patienten, die nicht reagieren, nicht kommunizieren und/oder die Temperatur
- Vorgaben entsprechend überwachen. • Überwachen Sie die kutanen Reaktionen der Patienten, die nicht in der Lage sind, zu reagieren, zu kommunizieren bzw. die Temperatur zu fühlen, alle 15 Minuten oder

nicht spüren können, mindestens alle

15 Minuten oder den vor Ort gültigen

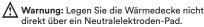
Passen Sie die Lufttemperatur an oder beenden Sie die Wärmetherapie, wenn das Therapieziel erreicht ist, erhöhte Temperaturen erfasst werden oder eine unerwünschte Hautreaktion im erwärmten Bereich auftritt.

gemäß den vor Ort gültigen Vorgaben.

- Die perforierte Seite der 3M™ Bair Hugger™-Wärmedecke (die Seite mit den kleinen Öffnungen) direkt auf die Haut des Patienten legen (Abbildung A).
- Gegebenenfalls das Trägermaterial vom Klebestreifen abziehen und die Wärmedecke auf der Haut festkleben (Abbildung B). Dies verhindert den Luftstrom in Richtung OP-Feld.

Optional: Ein Tuch oben auf die Wärmedecke legen, um die Effektivität zu erhöhen.

Warnung: Platzieren Sie keine Vorrichtungen zur Absicherung des Patienten (d. h. Sicherungsband oder Klebestreifen) über der Wärmedecke.



Setzen Sie das Ende des Schlauchs der Bair Hugger-Wärmeeinheit in den Schlauchanschluss ein (Abbildung C). Mit einer Drehbewegung eine gute Passung sicherstellen. Rund um den mittleren Bereich des Schlauchendes zeigt eine visuelle Markierung die richtige Einführtiefe des Schlauchs an. Den Schlauch stabilisieren, um eine sichere Befestigung zu gewährleisten.

Warnung: Führen Sie die Behandlung von Patienten nicht durch, indem Sie nur den Schlauch der Wärmeeinheit verwenden. Schließen Sie den Schlauch stets vor der Wärmetherapie an die Bair Hugger-Wärmedecke an.

#### Doc. 9112 valis: Filed 10/02/17 speziellen Überlegungen für Bair Hugger-Wärmedecken beachten.

Wählen Sie die gewünschte Temperatureinstellung an der Wärmeeinheit aus, um die Wärmetherapie zu starten. (Informationen zu Ihrem Modell der Wärmeeinheit finden Sie in der Bedienungsanleitung.)

🔨 Vorsicht: Empfehlungen zur Überwachung von Patienten:

• 3M empfiehlt, die Körperkerntemperatur kontinuierlich zu überwachen. Bei fehlender kontinuierlicher Überwachung die Temperatur von Patienten, die nicht reagieren, nicht kommunizieren und/oder die Temperatur nicht spüren können, mindestens alle 15 Minuten oder den vor Ort gültigen Vorgaben entsprechend überwachen.

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- Überwachen Sie die kutanen Reaktionen der Patienten, die nicht in der Lage sind, zu reagieren, zu kommunizieren bzw. die Temperatur zu fühlen, alle 15 Minuten oder gemäß den vor Ort gültigen Vorgaben.
- Passen Sie die Lufttemperatur an oder beenden Sie die Wärmetherapie, wenn das Therapieziel erreicht ist, erhöhte Temperaturen erfasst werden oder eine unerwünschte Hautreaktion im erwärmten Bereich auftritt.
- Schalten Sie je nach verwendeter Wärmeeinheit das Gerät aus oder in den Standby-Modus, um die Wärmetherapie abzubrechen. Trennen Sie den Schlauch von der Wärmedecke, und entsorgen Sie die Decke gemäß den Richtlinien des Krankenhauses.

### Spezielle Überlegungen:

Doppelanschluss für Torsodecken mit Doppelanschluss Modell 54200 Oberkörperdecken Modell 52200/52301 und Decken mit OP-Fenster Modell 57000

Zwei Schlauchansätze stehen zur Auswahl. Die abnehmbare Abdeckung in den Schlauchansatz einsetzen, der während der Wärmetherapie nicht verwendet wird (Abbildung D).

#### Kopfabdeckung für Torsodecken Modell 54000/54200, Oberkörperdecken Modell 52200/52301 und Decke mit OP-Fenster Modell 57000

Wenn der Patient intubiert ist und beatmet wird, die Kopfabdeckung über Kopf und Hals des Patienten legen (Abbildung E). Andernfalls die Abdeckung mit gewissem Abstand vom Kopf zwischen die Kanäle der Wärmedecke klemmen.

Marnung: Die Wärmedecke oder die Kopfabdeckung darf den Kopf oder die Atemwege des Patienten nicht verdecken wenn dieser nicht mechanisch beatmet wird.

#### Oberkörperdecken Modell 52200/52301 (optional)

An den Befestigungsstreifen ziehen, die sich mittig an der Ober- und Unterseite der Wärmedecke befinden. Diese Bänder befestigen, damit sich die aufgeblasene Decke nicht vom Patienten löst. Um die Oberkörperdecke mit einer Armlagerung verwenden zu können, kann eine Hälfte der Wärmedecke abgeschnürt werden, indem sie mit Klebeband umwickelt oder neben dem Patienten eingeklemmt wird (Abbildung F).

#### Chirurgische Ganzkörperdecke Modell 61000 und Mehrfachzugangsdecke Modell 31500

Für den Zugriff über die Zugänge die vorperforierte Lasche an der Seite der Wärmedecke abreißen. Das Trägermaterial vom Klebestreifen in der Mitte der Decke abziehen. Den Zugang zurückfalten und auf den Klebestreifen drücken. Zum Lösen des Zugangs diesen vom Klebestreifen abziehen (Abbildung G).

#### Decke mit Thoraxfenster Modell 30500

Die transparente Kunststoffabdeckung für die Versorgung im Oberkörperbereich zurückschlagen (Abbildung H).

3M, Bair Hugger und das Bair Hugger-Logo sind Marken von 3M.

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#### Indicazioni per l'uso

Il sistema per la gestione della temperatura 3M™ Bair Hugger™ è destinato alla prevenzione e al trattamento dell'ipotermia. Inoltre, può essere utilizzato per offrire comfort termico al paziente in condizioni in cui potrebbe avere troppo freddo o troppo caldo. Il sistema per la gestione della temperatura può essere utilizzato con pazienti adulti e pediatrici.

- NON STERILE.
- La legge federale degli Stati Uniti limita la vendita di questo dispositivo agli operatori sanitari abilitati o su prescrizione degli stessi.

#### Controindicazioni, avvertenze e precauzioni

#### Spiegazione delle conseguenze delle avvertenze



## **AVVERTENZA:**

indica una situazione pericolosa che, se non evitata, potrebbe comportare decesso o lesioni gravi.



#### ATTENZIONE:

indica una situazione pericolosa che, se non evitata, potrebbe causare lesioni di media o lieve entità.

#### CONTROINDICAZIONI: Per ridurre il rischio di lesioni termiche:

Non applicare calore agli arti inferiori durante il clampaggio aortico. L'applicazione di calore ad arti ischemici potrebbe causare lesioni termiche.

#### AVVERTENZA: Per ridurre il rischio di lesioni termiche:

- Non trattare pazienti soltanto con il tubo flessibile dell'unità riscaldante Bair Hugger. Collegare sempre il tubo flessibile a una coperta riscaldante Bair Hugger prima di iniziare la terapia di riscaldamento.
- Non permettere al paziente di sdraiarsi sul tubo flessibile dell'unità riscaldante.
- Evitare qualsiasi contatto diretto del tubo flessibile con la cute del paziente durante la terapia di riscaldamento.
- Durante la terapia di riscaldamento non lasciare soli neonati, bambini, ragazzi e altri pazienti vulnerabili.
- Durante una terapia di riscaldamento prolungata, monitorare costantemente i pazienti con scarsa perfusione.
- Non porre il lato non perforato della coperta riscaldante a contatto con il paziente. Porre sempre il lato perforato (con piccoli fori) direttamente sopra il paziente e a contatto con la sua cute.
- In sala operatoria, non utilizzare questa coperta riscaldante con dispositivi diversi da un'unità riscaldante Bair Hugger serie 500 o 700.
- Non utilizzare in sala operatoria un'unità riscaldante Bair Hugger serie 200.
- Non utilizzare unità riscaldanti Bair Hugger serie 800 regolabili dal paziente con le coperte riscaldanti Bair Hugger.
- Se si accende la spia rossa di surriscaldamento e si attiva l'allarme acustico, interrompere immediatamente la terapia di riscaldamento. Scollegare l'unità riscaldante e rivolgersi a un tecnico qualificato.
- Non posizionare un dispositivo di fissaggio del paziente (ad es. nastro o cinghia di sicurezza) sulla coperta riscaldante.
- Non posizionare la coperta riscaldante direttamente su un elettrodo dispersivo.

#### AVVERTENZA: Per ridurre il rischio di lesioni o decesso del paziente a causa di un'alterazione della quantità di farmaco somministrata:

 Non utilizzare una coperta riscaldante su cerotti di medicazione transdermici.

AVVERTENZA. Per ridurre il rischio di lesioni dovuto all'interferenza con la ventilazione:

• Evitare di coprire la testa del paziente con la coperta riscaldante o il telo per il capo e di ostruire le vie aeree quando il paziente non è ventilato meccanicamente.

#### AVVERTENZA: Per ridurre potenziali lesioni dovute a cadute dei pazienti:

 Non utilizzare la coperta riscaldante per trasferire o spostare il paziente.

#### ATTENZIONE: Per ridurre il rischio di contaminazione crociata:

 Questa coperta riscaldante non è sterile e deve essere utilizzata ESCLUSIVAMENTE su un singolo paziente. La presenza di un lenzuolo tra la coperta riscaldante e il paziente non serve a prevenire la contaminazione del prodotto.



#### ATTENZIONE: Per ridurre il rischio di incendio:

• Questo prodotto è classificato con grado di infiammabilità normale di classe I, in base alla definizione della normativa sull'infiammabilità dei tessuti 16 CFR 1610 della Commissione per la sicurezza dei beni di consumo. Seguire i protocolli di sicurezza standard quando si utilizzano fonti di calore a elevata intensità.



#### ATTENZIONE: Per ridurre il rischio di lesioni termiche:

• Non utilizzare se il confezionamento primario è stato precedentemente aperto o se risulta danneggiato.



### ATTENZIONE: Per ridurre il rischio di lesioni termiche, ipertermia o ipotermia:

- 3M consiglia di monitorare costantemente la temperatura centrale. In assenza di un monitoraggio continuo, controllare la temperatura dei pazienti che non siano in condizioni di reagire, di comunicare e/o che non siano sensibili alla temperatura almeno ogni 15 minuti o in base al protocollo in vigore.
- Monitorare le risposte cutanee dei pazienti che non siano in condizioni di reagire, di comunicare e/o che non siano sensibili alla temperatura almeno ogni 15 minuti o in base al protocollo in vigore.
- Regolare la temperatura dell'aria o interrompere la terapia una volta raggiunto l'obiettivo terapeutico, se si registrano temperature elevate o se si verifica una risposta cutanea avversa nell'area riscaldata.

#### Istruzioni

- Collocare il lato perforato della coperta riscaldante 3M™ Bair Hugger™ (con piccoli fori) sopra al paziente direttamente a contatto con la cute (Figura A).
- Laddove possibile, rimuovere il materiale protettivo dalla striscia adesiva e fare aderire la coperta termica al paziente (Figura B). In questo modo si impedisce all'aria di convergere verso il sito chirurgico.

Procedura opzionale: posizionare un lenzuolo o una coperta in tessuto sulla coperta riscaldante per incrementarne l'efficacia.

/!\ Avvertenza: Non posizionare un dispositivo di fissaggio del paziente (ad es. nastro o cinghia di sicurezza) sulla coperta riscaldante.

/ Avvertenza: Non posizionare la coperta riscaldante direttamente su un elettrodo dispersivo.

3. inserire l'estremità del tubo flessibile dell'unità riscaldante Bair Hugger nell'attacco per il tubo flessibile (Figura C). Per assicurare una tenuta salda, inserire il tubo con un movimento rotatorio. La tacca nella sezione centrale dell'estremità del tubo flessibile fornisce una guida per determinare fino a che punto inserire il tubo. Sostenere il tubo per ottenere un collegamento ben saldo.



Avvertenza: Non trattare pazienti soltanto con il tubo flessibile dell'unità riscaldante. Collegare sempre il tubo flessibile a una coperta riscaldante Bair Hugger prima di iniziare la terapia di riscaldamento.

NOTA: Vedere le considerazioni particolari per le coperte Bair Hugger mostrate di seguito

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desiderata sull'unità riscaldante per iniziare la terapia di riscaldamento (vedere il Manuale d'uso per il modello di unità riscaldante specifico).



Attenzione: Consigli per il monitoraggio del paziente:

- 3M consiglia di monitorare costantemente la temperatura centrale. In assenza di un monitoraggio continuo, controllare la temperatura dei pazienti che non siano in condizioni di reagire, di comunicare e/o che non siano sensibili alla temperatura almeno ogni 15 minuti o in base al protocollo in vigore.
- Monitorare le risposte cutanee dei pazienti che non siano in condizioni di reagire, di comunicare e/o che non siano sensibili alla temperatura almeno ogni 15 minuti o in base al protocollo in vigore.
- Regolare la temperatura dell'aria o interrompere la terapia una volta raggiunto l'obiettivo terapeutico, se si registrano temperature elevate o se si verifica una risposta cutanea avversa nell'area riscaldata.
- In base al modello di unità riscaldante utilizzato, spegnere l'unità o porla in modalità di standby per interrompere la terapia di riscaldamento. Scollegare il tubo flessibile dell'unità riscaldante dalla coperta riscaldante e smaltire quest'ultima in base alle politiche ospedaliere.

#### Considerazioni particolari:

Doppio attacco per i modelli 54200 coperta per il torace a doppio attacco, 52200/52301 coperte per la parte superiore del corpo, e 57000 coperta per l'accesso chirurgico

Sono presenti due attacchi per il tubo flessibile per consentire la scelta al medico. Posizionare la copertura dell'attacco per il tubo flessibile rimovibile nell'attacco per il tubo che non viene utilizzato durante la terapia di riscaldamento (Figura D).

per il torace, 52200/52301 coperte per la parte superiore del corpo, e 57000 coperta per l'accesso chirurgico

Se il paziente viene intubato e ventilato, poggiare il telo per il capo sulla testa e il collo del paziente (Figura E), altrimenti, infilare il telo tra i canali della coperta riscaldante, lontano dalla testa del paziente.



Avvertenza: Evitare di coprire la testa del paziente con la coperta riscaldante o il telo per il capo e di ostruire le vie aeree quando il paziente non è ventilato meccanicamente.

#### Modelli 52200/52301 coperte per la parte superiore del corpo (opzionale)

Tirare le linguette della fascetta di fissaggio lungo i bordi superiore e inferiore della coperta riscaldante. Annodare tali fascette per evitare che la coperta gonfiata si sollevi dal corpo del paziente. Per utilizzare la coperta per la parte superiore del corpo con un poggiabraccio, una metà della coperta riscaldante può essere annodata avvolgendovi del nastro o facendola passare al di sotto del paziente (Figura F).

#### Modelli 61000 coperta chirurgica corpo intero, e 31500 coperta post-operatoria con accesso multiplo

Per utilizzare i pannelli di accesso, strappare la linguetta non tagliata sul bordo della coperta riscaldante. Rimuovere il supporto del nastro adesivo al centro della coperta. Ripiegare il pannello di accesso e premere contro il nastro esposto. Rimuovere il pannello dal nastro per staccarlo (Figura G).

#### Modello 30500, coperta con accesso al torace

Sollevare il telo in plastica trasparente per operare sulla parte superiore del corpo del paziente (Figura H).

3M, Bair Hugger e il logo Bair Hugger sono marchi di fabbrica di 3M.

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# **(S) INSTRUCCIONES DE USO**

#### Indicaciones de uso

El sistema de gestión de la temperatura Bair Hugger™ de 3M™ está diseñado para prevenir y tratar la hipotermia. Asimismo, este sistema de gestión de la temperatura puede utilizarse para proporcionar confort térmico a los pacientes cuando existan condiciones que puedan provocar que estos tengan demasiado calor o demasiado frío. El sistema de gestión de la temperatura puede utilizarse tanto con pacientes adultos como pediátricos.

- NO ESTÉRIL.
- La ley federal (EE. UU.) restringe la venta de este dispositivo exclusivamente a un profesional sanitario con licencia o por prescripción de este.

#### Contraindicaciones, advertencias y precauciones

## Explicación de las palabras de advertencia



#### ADVERTENCIA:

Indica una situación de peligro que, si no se evita, podría ocasionar la muerte o una lesión grave.



## PRECAUCIÓN:

Indica una situación de peligro que, si no se evita, podría ocasionar heridas moderadas o leves.



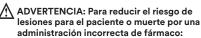
#### CONTRAINDICACIÓN: Para reducir el riesgo de lesión térmica:

 No aplique calor a las extremidades inferiores durante el clampaje transversal de la aorta. Si se aplica calor a las extremidades isquémicas, pueden producirse lesiones térmicas.

#### ADVERTENCIA: Para reducir el riesgo de lesión térmica:

- No aplique el tratamiento a los pacientes con la manguera de la unidad de calentamiento Bair Hugger solamente. Conecte siempre la manguera a una manta térmica Bair Hugger antes de aplicar la terapia de calentamiento.
- No permita que el paciente descanse sobre la manguera de la unidad de calentamiento.
- No permita que la manguera de la unidad de calentamiento entre en contacto directo

- con la piel del paciente durante la terapia de calentamiento.
- No deje a los neonatos, bebés, niños y otras poblaciones de pacientes vulnerables sin atención durante la terapia de calentamiento.
- No deje a los pacientes con una mala perfusión sin controlar durante una terapia prolongada de calentamiento.
- No coloque el lado no perforado de la manta térmica sobre el paciente. Coloque siempre el lado perforado (con orificios pequeños) directamente sobre el paciente en contacto con la piel del paciente.
- En el quirófano, no utilice esta manta térmica con ningún dispositivo que no sea una unidad de calentamiento Bair Hugger de las series 500 o 700
- No utilice una unidad de calentamiento Bair Hugger de la serie 200 en el quirófano.
- No utilice una unidad de calentamiento ajustable al paciente Bair Hugger de la serie 800 con ninguna manta térmica Bair Hugger.
- No continúe con la terapia de calentamiento si la luz roja indicadora de Over-temperature (Sobrecalentamiento) se enciende y suena la alarma. Desenchufe la unidad de calentamiento y póngase en contacto con un técnico cualificado del servicio técnico.
- No coloque el dispositivo de seguridad del paciente (es decir, la correa o cinta de seguridad) sobre la manta térmica.
- No coloque la manta térmica directamente sobre una placa electroquirúrgica.



• No utilice una manta térmica sobre parches de fármacos transdérmicos.



#### ADVERTENCIA. Para reducir el riesgo de lesiones debidas a interferencias con la ventilación:

 No permita que la manta térmica o la cubierta para la cabeza cubran la cabeza del paciente

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ventilación mecánica.



#### ADVERTENCIA: Para reducir la posibilidad de lesión por caídas del paciente:

No utilice una manta térmica para transferir o mover al paciente.



#### PRECAUCIÓN: Para reducir el riesgo de contaminación cruzada:

 Esta manta térmica no es estéril y está diseñada para usarse SOLO en un único paciente. La colocación de una sábana entre la manta térmica y el paciente no evita la contaminación del producto.



#### **│ PRECAUCIÓN: Para reducir el riesgo** de incendio:

• Este producto está clasificado como de clase I, inflamabilidad normal, de acuerdo con la definición de la normativa sobre telas inflamables de la comisión de seguridad sobre productos de consumo, 16 CFR 1610. Siga los protocolos de seguridad estándar cuando utilice fuentes de calor de gran intensidad.



#### PRECAUCIÓN: Para reducir el riesgo de lesión térmica:

 No lo utilice si el embalaje principal está dañado o se ha abierto anteriormente.



#### PRECAUCIÓN: Para reducir el riesgo de lesión térmica, hipertermia o hipotermia:

- 3M recomienda un control continuo de la temperatura interna. En ausencia de un control continuo, controle la temperatura de los pacientes que no puedan reaccionar o comunicarse, o que no puedan sentir la temperatura con una frecuencia mínima de 15 minutos o de acuerdo con el protocolo institucional.
- Controle las respuestas cutáneas de los pacientes que no puedan reaccionar o comunicarse, o que no puedan sentir la temperatura con una frecuencia mínima de 15 minutos o de acuerdo con el protocolo institucional.
- Si se registran temperaturas elevadas o si hay una respuesta cutánea adversa en la zona calentada, ajuste la temperatura del aire o interrumpa la terapia cuando se haya alcanzado el objetivo terapéutico.

#### Instrucciones

- Coloque el lado perforado (con orificios pequeños) de la manta térmica Bair Hugger™ de 3M™ directamente sobre el paciente en contacto con la piel del paciente (figura A).
- Cuando sea aplicable, retire la parte trasera de la cinta adhesiva y adhiera la manta térmica al paciente (figura B). Esto evita que el aire fluya hacia la zona quirúrgica.

Opcional: Coloque una sábana o protector de tela sobre la manta térmica para aumentar la efectividad.



Advertencia: No coloque el dispositivo de seguridad del paciente (es decir, la correa o cinta de seguridad) sobre la manta térmica.



Advertencia: No coloque la manta térmica directamente sobre una placa electroquirúrgica.

Introduzca el extremo de la manguera de 3. la unidad de calentamiento Bair Hugger en el puerto de la manguera (figura C). Realice un movimiento giratorio para garantizar un ajuste preciso de la manguera. Existe un marcador visual alrededor de la sección media del extremo de la manguera para guiar la profundidad de la inserción de la manguera. Sostenga la manguera para garantizar una conexión segura.



Advertencia: No aplique el tratamiento a los pacientes con la manguera de la unidad de calentamiento solamente. Conecte siempre la manguera a una manta térmica Bair Hugger antes de aplicar la terapia de calentamiento.

NOTA: Consulte las consideraciones especiales sobre las mantas Bair Hugger mostradas a continuación.

en la unidad de calentamiento para iniciar la terapia de calentamiento. (Consulte el manual del operador del modelo de la unidad de calentamiento específica).



#### Precaución: Recomendaciones sobre el control del paciente:

- 3M recomienda un control continuo de la temperatura interna. En ausencia de un control continuo, controle la temperatura de los pacientes que no puedan reaccionar o comunicarse, o que no puedan sentir la temperatura con una frecuencia mínima de 15 minutos o de acuerdo con el protocolo institucional.
- Controle las respuestas cutáneas de los pacientes que no puedan reaccionar o comunicarse, o que no puedan sentir la temperatura con una frecuencia mínima de 15 minutos o de acuerdo con el protocolo institucional.
- Si se registran temperaturas elevadas o si hay una respuesta cutánea adversa en la zona calentada, ajuste la temperatura del aire o interrumpa la terapia cuando se haya alcanzado el objetivo terapéutico.
- 5. En función del modelo de la unidad de calentamiento utilizado, apague la unidad o póngala en el modo en espera para interrumpir la terapia de calentamiento. Desconecte la manquera de la unidad de calentamiento de la manta térmica y deseche la manta de acuerdo con la política del hospital.

#### Consideraciones especiales:

Puerto doble para la manta para el torso con puerto doble modelo 54200, mantas para la parte superior del cuerpo 52200/52301 y manta con acceso quirúrgico 57000

Dos puertos de la manguera disponibles para satisfacer la preferencia del médico. Coloque el cartón extraíble del puerto de la manguera en el puerto de la manguera que no se esté utilizando durante la terapia de calentamiento (figura D).

Cubierta para la cabeza para mantas para el torso modelos 54000/54200, mantas para la parte superior del cuerpo 52200/52301 y manta con acceso quirúrgico 57000

Si el paciente está intubado y ventilado, coloque la cubierta para la cabeza sobre la cabeza y el cuello del paciente (figura E). De lo contrario, inserte la cinta entre los canales de la manta térmica, lejos de la cabeza del paciente.



Advertencia: No permita que la manta térmica o la cubierta para la cabeza cubran la cabeza del paciente o la vía de aire cuando el paciente no reciba ventilación mecánica.

#### Mantas para la parte superior del cuerpo modelos 52200/52301 (opcionales)

Tire de las pestañas de las tiras de amarre, centradas a lo largo de los bordes superior e inferior de la manta térmica. Amarre estas tiras para evitar que la manta inflada se levante del paciente. Para utilizar la manta para la parte superior del cuerpo con un reposabrazos, una mitad de la manta térmica puede estar amarrada mediante esparadrapo alrededor de este o insertándola por debajo del paciente (figura F).

#### Mantas quirúrgicas de cuerpo completo modelo 61000 y mantas multiacceso para el posoperatorio modelo 31500

Para utilizar los paneles de acceso, rasgue la pestaña sin cortar del borde de la manta térmica. Retire la parte trasera de la cinta adhesiva situada en el centro de la manta. Pliegue el panel de acceso hacia atrás y presiónelo contra la cinta expuesta. Tire del panel en dirección contraria a la cinta para retirarlo (figura G).

#### Manta de acceso al tórax modelo 30500

Levante la cubierta de plástico transparente para suministrar cuidados al paciente en la zona superior del cuerpo (figura H).

3M, Bair Hugger y el logotipo de Bair Hugger son marcas registradas de 3M.

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#### Indicaties voor gebruik

Het 3M™ Bair Hugger™-temperatuurregelsysteem is bedoeld voor het voorkomen en behandelen van hypothermie. Bovendien kan het temperatuurregelsysteem worden gebruikt om de patiënt thermisch comfort te bieden wanneer zich omstandigheden voordoen waarbij patiënten te warm of te koud kunnen worden. Het . temperatuurregelsysteem kan worden gebruikt voor zowel volwassen patiënten als kinderen.

- NIFT STERIFI
- Volgens de federale wetgeving van de VS mag dit product uitsluitend worden verkocht door of op voorschrift van een erkend professioneel zorgverlener.

#### Contra-indicaties, waarschuwingen en voorzorgsmaatregelen

#### Uitleg van waarschuwingen voor gevolgen



#### WAARSCHUWING:

duidt een gevaarlijke situatie aan die, indien deze niet wordt vermeden, de dood of ernstig letsel tot gevolg kan hebben.



# /!\ LET OP:

duidt een gevaarlijke situatie aan die, indien deze niet wordt vermeden, gering of matig letsel tot gevolg kan hebben.



#### CONTRA-INDICATIE: om het risico op thermisch letsel te beperken:

 Verwarm de onderste extremiteiten niet tiidens het klemmen van de aorta. Er kan thermisch letsel ontstaan wanneer ischemische ledematen worden verwarmd.



# WAARSCHUWING: om het risico op thermisch letsel te beperken:

- Behandel patiënten niet alleen met de slang van de Bair Hugger-verwarmingsunit. Sluit de slang altijd aan op een Bair Hugger-warmtedeken voordat u begint met de warmtetherapie.
- Laat de patiënt niet op de slang van de verwarmingsunit liggen.
- Zorg dat de slang van de verwarmingsunit niet rechtstreeks in contact komt met de huid van de patiënt tijdens de warmtetherapie.
- Laat pasgeborenen, peuters, kinderen en andere kwetsbare patiënten niet onbewaakt achter tijdens de warmtetherapie.
- Laat patiënten met zwakke perfusie niet onbewaakt achter tijdens langdurige warmtetherapie.
- Plaats de niet-geperforeerde kant van de warmtedeken niet op de patiënt. Plaats de geperforeerde kant (met de kleine gaatjes) altijd rechtstreeks op de patiënt, zodat de deken in contact staat met de huid van de patiënt.
- Gebruik deze warmtedeken in de operatiekamer niet met een ander product dan een Bair Hugger-verwarmingsunit van de 500- of 700-serie.
- Gebruik Bair Hugger serie 200-verwarmingsunits niet in operatiekamers.
- Gebruik Bair Hugger patiënt-instelbare verwarmingsunits van de 800-serie niet in combinatie met een Bair Hugger-warmtedeken.
- Ga niet verder met de warmtetherapie als het rode controlelampje voor oververhitting gaat branden en het alarm klinkt. Trek de stekker van de verwarmingsunit uit het stopcontact en waarschuw een bevoegd onderhoudstechnicus.
- Plaats geen hulpmiddel om de patiënt op zijn plaats te houden (d.w.z. een veiligheidsband of tape) over de warmtedeken.
- Plaats de warmtedeken niet rechtstreeks op een dispergerende-elektrodenpad.

WAARSCHUWING: om het risico op overlijden van de patiënt of letsel als gevolg van een veranderde medicijntoediening te beperken:

 Gebruik warmtedekens niet op pleisters voor transdermale medicatietoediening.



wordt beademd.

letsel als gevolg van interferentie met kunstmatige beademing te beperken: De warmtedeken of het hoofdlaken mag het hoofd of de luchtwegen van de patiënt niet

bedekken wanneer de patiënt niet kunstmatig

## MAARSCHUWING: om het risico op letsel door vallen van de patiënt te verminderen:

• Gebruik een warmtedeken niet om de patiënt over te brengen of te verplaatsen.

### LET OP: om het risico op kruisbesmetting te beperken:

 Deze warmtedeken is niet steriel en is UITSLUITEND bestemd voor gebruik bij één patiënt. Het gebruik van een laken tussen een warmtedeken en de patiënt voorkomt geen besmetting van het product.



#### LET OP: om het risico op brand te beperken:

• Dit product is geclassificeerd als een Klasse I-apparaat met normale ontvlambaarheid zoals bepaald in verordening ontvlambare stoffen 16 CFR 1610 van de U.S. Consumer Product Safety Commission (productveiligheidscommissie van de Verenigde Staten). Houd u aan de standaard veiligheidsprotocollen wanneer u warmtebronnen met hoge intensiteit gebruikt.



#### LET OP: om het risico op thermisch letsel te beperken:

 Niet gebruiken als de primaire verpakking eerder geopend of beschadigd is.



#### LET OP: om het risico op thermisch letsel, hyperthermie of hypothermie te beperken:

- 3M adviseert u de kerntemperatuur van de patiënt continu te monitoren. Als er geen continue monitoring plaatsvindt, controleer de temperatuur van patiënten die niet in staat zijn te reageren, communiceren en/of geen gevoelssensatie hebben dan minimaal elke 15 minuten of volgens het protocol van uw instelling.
- Controleer de huidreactie van patiënten die niet in staat zijn te reageren, communiceren en/of geen gevoelssensatie hebben minimaal elke 15 minuten of volgens het protocol van uw instelling.
- Pas de luchttemperatuur aan of staak de therapie wanneer het therapeutische doel bereikt is, verhoogde temperaturen worden geregistreerd of een ongewenste huidreactie optreedt in het verwarmde gebied.

#### Instructies

- Plaats de geperforeerde kant (met de kleine gaatjes) van de 3M™ Bair Hugger™-warmtedeken altijd rechtstreeks op de patiënt, zodat de deken in contact staat met de huid van de patiënt (Afbeelding A).
- Verwijder eventueel de beschermfolie van de kleefstrip en bevestig de warmtedeken aan de patiënt (afbeelding B). Hierdoor kan er geen lucht naar de operatiewond stromen.

Optioneel: Er kan een stoffen deken of laken bovenop de warmtedeken worden geplaatst om de werkzaamheid te verhogen.



Maarschuwing: Plaats geen hulpmiddel om de patiënt op zijn plaats te houden (d.w.z. een veiligheidsband of tape) over de warmtedeken.

/ Waarschuwing: Plaats de warmtedeken niet rechtstreeks op een dispergerende-elektrodenpad.

Steek het uiteinde van de slang van de Bair Hugger-verwarmingsunit in de slangpoort (afbeelding C). Maak een draaiende beweging om deze goed aan te sluiten. Er is een markering aangebracht rondom het midden van het uiteinde van de slang om aan te geven hoe diep de slang in de poort moet worden gestoken. Ondersteun de slang om te zorgen voor een goede bevestiging.

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alleen met de slang van de verwarmingsunit. Sluit de slang altijd aan op een Bair Hugger-warmtedeken voordat u begint met de warmtetherapie.

#### OPMERKING: Raadpleeg de bijzondere overwegingen voor Bair Hugger-dekens hieronder.

Selecteer de gewenste temperatuur op de verwarmingsunit om te beginnen met de warmtetherapie. (Raadpleeg de bedieningshandleiding voor specifieke informatie over uw model verwarmingsunit).



Let op: Aanbevelingen voor monitoring van patiënten:

- 3M adviseert u de kerntemperatuur van de patiënt continu te monitoren. Als er geen continue monitoring plaatsvindt, controleer de temperatuur van patiënten die niet in staat zijn te reageren, communiceren en/of geen gevoelssensatie hebben dan minimaal elke 15 minuten of volgens het protocol van uw instelling.
- Controleer de huidreactie van patiënten die niet in staat zijn te reageren, communiceren en/of geen gevoelssensatie hebben minimaal elke 15 minuten of volgens het protocol van uw instelling.
- Pas de luchttemperatuur aan of staak de therapie wanneer het therapeutische doel bereikt is, verhoogde temperaturen worden geregistreerd of een ongewenste huidreactie optreedt in het verwarmde gebied.
- Afhankelijk van het model verwarmingsunit dat u gebruikt, dient u de unit uit of in stand-bymodus te zetten om de warmtetherapie te staken. Maak de slang van de verwarmingsunit los van de warmtedeken en voer de deken af volgens het beleid van uw instelling.

#### Bijzondere overwegingen:

Twee poorten voor de Warmtedeken thorax (dual port) model 54200, Warmtedekens bovenlichaam model 52200/52301 en Surgical Access warmtedeken model 57000

Er zijn twee slangpoorten aanwezig, zodat de clinicus de gewenste poort kan kiezen. Plaats de uitneembare

#### gebruikt tijdens de warmtetherapie (afbeelding D). Hoofdlaken voor de Warmtedekens thorax model 54000/54200, Warmtedekens bovenlichaam model 52200/52301 en Surgical Access

warmtedeken model 57000 Als de patiënt geïntubeerd is en beademd wordt,

legt u het hoofdlaken over het hoofd en de hals van de patiënt (Afbeelding E). Als dit niet het geval is, stopt u het hoofdlaken weg tussen de kanalen van de warmtedeken, uit de buurt van het hoofd van de patiënt.



/!\ Waarschuwing: De warmtedeken of het hoofdlaken mag het hoofd of de luchtwegen van de patiënt niet bedekken wanneer de patiënt niet kunstmatig wordt beademd.

#### Warmtedekens bovenlichaam model 52200/52301 (optioneel)

Trek aan de lipjes van de bevestigingsbanden langs de boven- en onderrand van de warmtedeken. Bind deze banden vast om ervoor te zorgen dat de opgeblazen warmtedeken op de patiënt blijft liggen. Om de deken voor het bovenlichaam met één armsteun te gebruiken, kunt u de helft van de warmtedeken afbinden door er tape omheen te wikkelen of deze onder de patiënt te stoppen (afbeelding F).

#### Chirurgisch warmtedeken hele lichaam model 61000 en Multi Access warmtedeken model 31500

Om de toegangspanelen te gebruiken, scheurt u het niet-ingesneden lipje bij de rand van de warmtedeken af. Verwijder de beschermlaag van de kleefstrip in het midden van de warmtedeken. Vouw het toegangspaneel terug en druk deze op de kleefstrip. Trek het paneel van de kleefstrip af om het los te maken (Afbeelding G).

#### Chest Access warmtedeken model 30500

Til de transparante kunststof bedekking op om het bovenlichaam van de patiënt te verzorgen (Afbeelding H).

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## SE BRUKSANVISNING

#### Indikationer för användning

3M™ Bair Hugger™ temperaturregleringssystem är avsett att förhindra och behandla hypotermi. Dessutom kan temperaturregleringssystemet användas för att ge patienten termisk komfort vid förhållanden som kan innebära att patienter känner sig för varma eller för kalla. Temperaturregleringssystemet kan användas på vuxna och pediatriska patienter.

- F.I.STERILT
- Enligt amerikansk federal lagstiftning får denna produkt endast säljas till eller på ordination av licensierad siukvårdspersonal.

#### Kontraindikationer, varningar och försiktighetsåtgärder

## Varningstexternas innebörd



#### VARNING!

Anger en farlig situation som, om den inte undviks, kan leda till dödsfall eller allvarliga personskador.



#### FÖRSIKTIGHET!

Anger en farlig situation som, om den inte undviks, kan leda till lindriga eller måttliga personskador.



#### KONTRAINDIKATION: För att minska risken för termisk skada:

 Under avklämning av aorta får de nedre extremiteterna ej utsättas för uppvärmning. Termisk skada kan uppstå vid uppvärmning av ischemiska kroppsdelar.



#### VARNING! För att minska risken för termisk skada:

Patienter får inte behandlas med enbart Bair Hugger-uppvärmningsslangen. Anslut alltid slangen till ett Bair Hugger-värmetäcke innan värmebehandling ges.

- Patienten får inte ligga ovanpå uppvärmningsslangen.
- Uppvärmningsslangen får inte komma i direktkontakt med patientens hud under värmebehandling.
- Lämna inte nyfödda, spädbarn, barn eller andra sårbara patientgrupper utan uppsikt under värmebehandling.
- Patienter med dålig cirkulation får inte lämnas utan övervakning vid långvarig värmebehandling.
- Värmetäckets operforerade sida får inte placeras mot patienten. Placera alltid den perforerade sidan (sidan med små hål) direkt ovanpå patienten och se till att denna sida har kontakt med patientens hud.
- I operationssalen får detta värmetäcke inte användas tillsammans med någon annan värmeanordning än modeller i Bair Hugger 500- och 700-serierna.
- Värmeanordningar i Bair Hugger 200-serien får inte användas i operationssalar.
- Patientjusterade värmeanordningar i Bair Hugger 800-serien får inte användas tillsammans med Bair Hugger-värmetäcken.
- Avbryt värmebehandlingen om den röda övertemperaturindikatorn tänds och larmsignalen ljuder. Koppla ur värmeenheten och kontakta en kvalificerad servicetekniker.
- Placera inte patientsäkerhetsanordningar (t.ex. säkerhetsrem eller tejp) över värmetäcket.
- Placera inte värmetäcket direkt ovanpå en dispergerande elektroddyna.

/ VARNING! För att minska risken för patientskada eller dödsfall till följd av . förändrad läkemedelstillförsel:

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transdermala läkemedelsplåster.



#### NARNING. För att minska risken för personskada till följd av ventilationsstörningar:

 Låt inte värmetäcket eller huvuddraperingen täcka patientens huvud eller luftvägar när patienten inte ventileras mekaniskt.



#### NARNING! För att minska risken för personskada till följd av patientfall:

Använd inte värmetäcket för att lyfta eller förflytta patienten.



### ∑ FÖRSIKTIGHET! För att minska risken för korskontaminering:

 Värmetäcket är inte sterilt och är ENDAST avsett för bruk på en patient. Det är inte möjligt att förhindra kontaminering av produkten genom att lägga ett lakan mellan värmetäcket och patienten.



#### ↑ FÖRSIKTIGHET! För att minska risken för brand:

• Denna produkt klassificeras som Klass I, normal antändlighet (Class I, Normal Flammability) enligt definitionen i förordningen om antändliga textilier; Consumer Products Safety Commission, 16 CFR 1610. Följ gällande säkerhetsbestämmelser vid användning av högintensiva värmekällor.



#### ♠ FÖRSIKTIGHET! För att minska risken för termisk skada:

 Produkten får inte användas om den primära förpackningen har öppnats eller är skadad.



### FÖRSIKTIGHET! För att minska risken för termisk skada, hypertermi eller hypotermi:

- 3M rekommenderar att kärntemperaturen övervakas kontinuerligt. Om kontinuerlig övervakning inte kan utföras ska temperaturen hos patienter som är inkapabla att reagera, kommunicera och/ eller inte kan känna temperaturen övervakas minst var 15:e minut eller i enlighet med inrättningens riktlinjer.
- Övervaka kutan respons hos patienter som är inkapabla att reagera, kommunicera och/eller inte kan känna temperaturen minst var 15:e minut eller i enlighet med inrättningens riktlinjer.
- Justera lufttemperaturen eller avbryt behandlingen när behandlingsmålet har uppnåtts, om förhöjda temperaturer registreras eller om en oönskad kutan respons observeras vid det uppvärmda området.

#### Anvisningai

- Placera den perforerade sidan av 3M™ Bair Hugger™ värmetäcke (sidan med små hål) direkt ovanpå patienten och se till att täcket har kontakt med patientens hud (figur A).
- Avlägsna om tillämpligt skyddet från tejpremsan och vidhäfta värmetäcket vid patienten (figur B). Detta förhindrar att luft flödar mot operationsstället.

Valfritt: Placera ett tygtäcke eller ett lakan över värmetäcket för att öka dess effektivitet.



#### Varning! Placera inte patientsäkerhetsanordningar (t.ex.



#### säkerhetsrem eller tejp) över värmetäcket. Narning! Placera inte värmetäcket direkt ovanpå en dispergerande elektroddyna.

Anslut ena änden av Bair Hugger-värmeenhetens slang till slangporten (figur C). Vrid fast slangen med en roterande rörelse för att se till att den sitter ordentligt. Det finns en visuell markör runt mitten av slangänden som ger vägledning avseende hur djupt slangen ska föras in. Stöd slangen för att försäkra att den är stadigt fixerad.

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enbart värmeenhetens slang. Anslut alltid slangen till ett Bair Hugger-värmetäcke innan värmebehandling ges.

#### Obs! Se särskilda övervägningar avseende Bair Hugger-täcken nedan.

Välj önskad temperaturinställning på värmeenheten och inled värmebehandlingen. (Se användarhandboken till den specifika värmeenhetsmodellen.)



#### / Försiktighet! Rekommendationer avseende patientövervakning:

- 3M rekommenderar att kärntemperaturen övervakas kontinuerligt. Om kontinuerlig övervakning inte kan utföras ska temperaturen hos patienter som är inkapabla att reagera, kommunicera och/eller inte kan känna temperaturen övervakas minst var 15:e minut eller i enlighet med inrättningens riktlinjer.
- Övervaka kutan respons hos patienter som är inkapabla att reagera, kommunicera och/eller inte kan kan a temperaturen minst var 15:e minut eller i enlighet med inrättningens riktlinjer.
- Justera lufttemperaturen eller avbryt behandlingen när behandlingsmålet har uppnåtts, om förhöjda temperaturer registreras eller om en oönskad kutan respons observeras vid det uppvärmda området.
- 5. Stäng av enheten eller försätt den i standbyläge för att avbryta värmebehandlingen, beroende på vilken enhetsmodell som används. Koppla bort värmeenhetens slang från värmetäcket och kassera täcket enligt inrättningens riktlinjer.

## Särskilda överväganden:

#### Dubbla portar för torsotäcke med dubbla portar modell 54200, överkroppstäcken modell 52200/52301 och bucaccesstäcke modell 57000

Två slangportar varav klinikern kan välja endera efter önskemål. Placera det löstagbara slangportskyddet i den slangport som inte används under värmebehandlingen (figur D).

#### Huvuddrapering för torsotäcken modell 54000/54200, överkroppstäcken modell 52200/52301 och bukaccesstäcke modell 57000

Om patienten är intuberad och ventileras ska huvuddraperingen läggas över patientens huvud och hals (figur E). I annat fall ska draperinger vikas in mellan värmetäckets kanaler, bort från patientens huvud.



Varning! Låt inte värmetäcket eller huvuddraperingen täcka patientens huvud eller luftvägar när patienten inte ventileras mekaniskt.

#### Överkroppstäcken av modell 52200/52301 (valfritt)

Dra i knytbandens flikar som är centrerade längs med den övre och nedre kanten av värmetäcket. Knyt dessa band för att undvika att det uppblåsta täcket glider av patienten. Om du vill använda överkroppstäcket med ett armstöd kan halva värmetäcket vikas bort och fästas genom att vira tejp runt täcket eller genom att vika in det under patienten (figur F).

#### Kirurgiskt helkroppstäcke modell 61000 och postoperativt multiaccesstäcke modell 31500

Om åtkomstpanelerna ska användas, riv den oskurna fliken vid värmetäckets kant. Avlägsna det skyddet från tejpremsan vid täckets mittdel. Vik tillbaka åtkomstpanelen och tryck den mot tejpen. Dra panelen bort från tejpen för att frigöra den (figur G).

#### Postop thoraxtäcke modell 30500

Lyft den genomskinliga plastdraperingen för åtkomst till patientens överkropp (figur H).

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### BRUGSANVISNING

#### Indikationer for brug

3M™ Bair Hugger™ temperaturstyringssystem er beregnet til at forebygge og behandle hypotermi. Derudover kan temperaturstyringssystemet bruges til at give patienten varmekomfort under forhold, der kan få patienter til at have det for varmt eller for koldt. Temperaturstyringssystemet kan bruges til voksne og pædiatriske patienter. 12

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- · Ifølge amerikansk lovgivning må dette produkt kun sælges eller ordineres af autoriseret sundhedspersonale.

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#### Forklaring på signalordskonsekvenser



ADVARSEL:
Indikerer en farlig situation, der kan resultere i dødsfald eller alvorlig personskade, hvis den ikke undgås.



#### **FORSIGTIG:**

Indikerer en farlig situation, der kan resultere i mindre eller moderat personskade, hvis den ikke undgås.



#### ★ KONTRAINDIKATION: For at reducere risikoen for varmeskade:

 Tilfør ikke varme til underekstremiteterne under aortisk krydsafklemning. Der kan forekomme termiske skader, hvis der tilføres varme til iskæmiske lemmer.



#### ADVARSEL: For at reducere risikoen for varmeskade:

- Behandl ikke patienter med Bair Hugger varmeenhedsslangen alene. Fastgør altid slangen til et Bair Hugger varmetæppe, inden der gives varmeterapi.
- Lad ikke patienten ligge på varmeenhedsslangen.
- Lad ikke varmeenhedsslangen komme i direkte kontakt med patientens hud under varmeterapien.
- Lad ikke nyfødte, spædbørn, børn og andre sårbare patientgrupper være uden opsyn under varmeterapien.
- Lad ikke patienter med ringe blodgennemstrømning være uovervåget under længerevarende varmeterapi.
- Placer ikke varmetæppets ikke-perforerede side på patienten. Placer altid den perforerede side (med de små huller) direkte oven på patienten i kontakt med patientens hud.
- På operationsstuen må dette varmetæppe ikke anvendes med nogen anden anordning end en Bair Hugger 500- eller 700-serie varmeenhed.
- Anvend ikke en Bair Hugger 200-serie varmeenhed på operationsstuen.
- Anvend ikke en Bair Hugger 800-serie justerbar varmeenhed til patienter med noget Bair Hugger varmetæppe.
- Fortsæt ikke varmeterapien, hvis den røde indikatorlampe for overtemperatur lyser, og alarmen lyder. Træk varmeenheden ud af stikkontakten, og kontakt en kvalificeret servicetekniker.
- Placer ikke patientfastgørelsesanordningen (dvs. sikkerhedsstrop eller tape) over varmetæppet.
- Placer ikke varmetæppet direkte over en dispersiv elektrodepude.



#### / ADVARSEL: For at reducere risikoen for patientskade eller -dødsfald som følge af ændret medicintilførsel:

 Anvend ikke et varmetæppe over transdermale medicinplastre.



#### ADVARSEL. For at reducere risikoen for skade som følge af interferens af ventilation:

Lad ikke varmetæppet eller hovedafdækningen dække patientens hoved eller luftveje, når patienten ikke er mekanisk ventileret.



#### ADVARSEL: For at reducere potentialet for personskade som følge af patientfald:

Anvend ikke et varmetæppe til at overføre eller flytte patienten.



#### N FORSIGTIG: For at reducere risikoen for krydskontaminering:

 Dette varmetæppe er ikke sterilt og er KUN beregnet til brug til én patient. Placering af et lagen mellem varmetæppet og patienten forhindrer ikke kontaminering af produktet.



#### FORSIGTIG: For at reducere risikoen for brand:

#### Klasse I Normal brændbarhed som defineret af den amerikanske Consumer Product Safety Commissions regulativ for brændbart stof, 16 CFR 1610. Følg standardsikkerhedsprotokoller ved brug af varmekilder med høj intensitet.

### FORSIGTIG: For at reducere risikoen for varmeskade:

• Undlad anvendelse, hvis den primære emballage tidligere har været åbnet eller er beskadiget.

#### FORSIGTIG: For at reducere risikoen for varmeskade, hypertermi eller hypotermi:

- 3M anbefaler konstant overvågning af kernetemperaturen. Hvis ikke der overvåges konstant, skal temperaturen overvåges hos patienter, som ikke er i stand til at reagere, kommunikere, og/eller som ikke kan føle temperatur, mindst hvert 15. minut eller i henhold til hospitalets protokol.
- Overvåg kutane reaktioner hos patienter, som ikke er i stand til at reagere, kommunikere, og/eller som ikke kan føle temperatur, mindst hvert 15. minut eller i henhold til hospitalets protokol.
- Juster lufttemperaturen, eller indstil behandlingen, når behandlingsmålet er nået, hvis der registreres forhøjede temperaturer, eller hvis der er en uønsket, kutan reaktion i det opvarmede område.

#### Veiledning

- Placer 3M™ Bair Hugger™ varmetæppets perforerede side (siden med små huller) direkte oven på patienten i kontakt med patientens hud (Figur A).
- Hvor det er relevant, fjernes beskyttelsesfilmen fra klæbestrimlen, og varmetæppet klæbes til patienten (Figur B). Det forhindrer luft i at strømme mod operationsområdet.

Valgfrit: Placer ét stoftæppe eller -lagen oven på varmetæppet for at øge effektiviteten.



Advarsel: Placer ikke patientfastgørelsesanordningen (dvs. sikkerhedsstrop eller tape) over varmetæppet.

Advarsel: Placer ikke varmetæppet direkte over en dispersiv elektrodepude.

Sæt enden af Bair Hugger varmeenhedens slange i slangeåbningen (Figur C). Brug en vridebevægelse til at sikre, at den sidder godt fast. Der er et visuelt mærke omkring midten af slangeenden til at lede dybden af slangeindføringen. Støt slangen for at sikre, at den sidder godt fast.



Advarsel: Behandl ikke patienter med varmeenhedsslangen alene. Fastgør altid slangen til et Bair Hugger varmetæppe, inden der gives varmeterapi.

#### BEMÆRK: Se særlige forbehold for Bair Hugger tæpper vist nedenfor.

Vælg den ønskede temperaturindstilling på varmeenheden for at starte varmeterapien. (Se betjeningsmanualen til din specifikke varmeenhedsmodel)



#### Forsigtig: Anbefalinger til patientovervågning:

- 3M anbefaler konstant overvågning af kernetemperaturen. Hvis ikke der overvåges konstant, skal temperaturen overvåges hos patienter, som ikke er i stand til at reagere. kommunikere, og/eller som ikke kan føle temperatur, mindst hvert 15. minut eller i henhold til hospitalets protokol.
- Overvåg kutane reaktioner hos patienter, som ikke er i stand til at reagere, kommunikere, og/eller som ikke kan føle temperatur, mindst hvert 15. minut eller i henhold til hospitalets protokol.
- Juster lufttemperaturen, eller indstil behandlingen, når behandlingsmålet er nået, hvis der registreres forhøjede temperaturer, eller hvis der er en uønsket, kutan reaktion i det opvarmede område.
- Baseret på den anvendte varmeenhedsmodel skal enheden slukkes eller sættes i standby for at indstille varmeterapien. Kobl varmeenhedens slange fra varmetæppet, og bortskaf tæppet i henhold til hospitalets politik.

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Dobbelt åbning til model 54200 tæppe med dobbelt åbning til torso, 52200/52301 tæpper til overkroppen og 57000 tæppe med kirurgisk adgang

Der er to slangeåbninger til det kliniske personales præference. Sæt det udtagelige slangeåbningskort i den slangeåbning, som ikke anvendes under varmeterapien (Figur D).

#### Hovedafdækning til model 54000/54200 tæpper til torso, 52200/52301 tæpper til overkroppen og 57000 tæppe med kirurgisk adgang

Hvis patienten er intuberet og ventileret, lægges hovedafdækningen over patientens hoved og hals (Figur E); ellers stoppes afdækningen mellem varmetæppets kanaler, væk fra patientens hoved.



Advarsel: Lad ikke varmetæppet eller hovedafdækningen dække patientens hoved eller luftveje, når patienten ikke er mekanisk ventileret.

Model 52200/52301 tæpper til overkroppen (valgfrie)

øverste og nederste kant. Bind disse bånd for a forhindre det luftfyldte tæppe i at løfte sig fra patienten. For at anvende tæppet til overkroppen med én armskinne kan den ene halvdel af varmetæppet holdes væk ved at vikle tape omkring den eller stoppe den under patienten (Figur F).

#### Model 61000 tæpper til helkrop, kirurgisk og 31500 tæpper til postoperativ multiadgang

For at bruge adgangspanelerne rives den hele flig ved varmetæppets kant over. Fjern beskyttelsesfilmen fra tapestrimlen midt på tæppet. Fold adgangspanelet tilbage, og tryk det mod den blotlagte tape. Træk panelet væk fra tapen for at løsne (Figur G).

#### Model 30500 tæppe med adgang til brystet

Løft den gennemsigtige plastikafdækning for at yde patientpleje til overkropsområdet (Figur H).

3M, Bair Hugger og Bair Hugger-logoet er varemærker tilhørende 3M.

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## M BRUKSANVISNING

#### Indikasioner for bruk

3M™ Bair Hugger™ temperaturstyringssystem er ment til å forebygge og behandle hypotermi. I tillegg kan temperaturstyringssystemet brukes til å gi pasienten varmekomfort når det foreligger forhold som kan føre til at pasienter føler seg for varme eller for kalde. Temperaturstyringssystemet kan brukes på voksne og pediatriske pasienter.

- IKKE STERILT.
- Føderal lov (USA) begrenser denne enheten til salg av, eller på bestilling av, lisensiert helsepersonell.

#### Kontraindikasjoner, advarsler og forsiktighetsregler

#### Forklaring av terminologi



#### ADVARSEL:

Indikerer en farlig situasjon som, om den ikke unngås, kan føre til død eller alvorlig personskade.



## FORSIKTIG:

Indikerer en farlig situasjon som, hvis den ikke unngås, kan føre til mindre eller middels alvorlig personskade.



#### ⚠ KONTRAINDIKASJONER: For å redusere risikoen for termiske skader:

 Ikke varm opp nedre ekstremiteter under bruk av en aortaklemme. Termiske skader kan oppstå hvis varme påføres iskemiske lemmer.

#### ADVARSEL: For å redusere risikoen for termiske skader:

- Ikke behandle pasienter kun med slangen til Bair Hugger-varmeenheten. Fest alltid slangen til et Bair Hugger-varmeteppe før du gir varmebehandling.
- Ikke la pasienten ligge på varmeenhetens slange.
- Ikke la varmeenhetens slange komme i direkte kontakt med pasientens hud under varmebehandling.
- Ikke forlat nyfødte, spedbarn, barn og andre sårbare pasientgrupper uten tilsyn under varmebehandling.
- Ikke forlat pasienter med dårlig perfusjon uovervåket under langvarig varmebehandling.
- Ikke legg den ikke-perforerte siden av varmeteppet på pasienten. Legg alltid den perforerte siden (med små hull) rett oppå pasienten i kontakt med pasientens hud.
- I operasjonssalen skal ikke dette varmeteppet brukes med andre enheter enn en Bair Hugger-varmeenhet i 500- eller 700-serien.
- Ikke bruk en Bair Hugger-varmeenhet i 200-serien i operasjonssalen.
- Ikke bruk en Bair Hugger-pasientjusterbar varmeenhet i 800-serien sammen med et Bair Hugger-varmeteppe.
- Ikke fortsett varmebehandling hvis den røde indikatorlampen for over-temp. begynner å

lyse og alarmen går. Koble fra varmeenheten og kontakt en kvalifisert servicetekniker.

- Ikke plasser en pasientfesteanordning (dvs. sikkerhetstropp eller tape) over varmeteppet.
- Ikke legg varmeteppet direkte over et dispersivt elektrodeplaster.



#### \Lambda ADVARSEL: For å redusere risikoen for pasientskade eller dødsfall som følge av endret levering av legemidler:

• Ikke bruk et varmeteppe over depotplastre for medisin.

#### / ADVARSEL. For å redusere risikoen for personskade forårsaket av interferens med ventilasion:

• Ikke la varmeteppet eller hodeoppdekkingen dekke pasientens hode eller luftveier når pasienten ikke blir mekanisk ventilert



#### ADVARSEL: For å redusere muligheten for personskade forårsaket av at pasienten faller:

• Ikke bruk et varmeteppe til å flytte eller løfte pasienten.



### M FORSIKTIG: For å redusere risikoen for krysskontaminering:

 Dette varmeteppet er ikke sterilt og er ment for bruk på KUN én pasient. Å legge et laken mellom varmeteppet og pasienten hindrer ikke smitteføring mellom pasienten og produktet.



#### ↑ FORSIKTIG: For å redusere risikoen for brann:

• Dette produktet er klassifisert som normalt antennelig i klasse I, som definert av den amerikanske etaten Consumer Product Safety Commission sine reguleringer for brannfarlig stoff, 16 CFR 1610. Følg standard sikkerhetsprotokoller når du bruker varmekilder med høy intensitet.



#### ♠ FORSIKTIG: For å redusere risikoen for termiske skader:

 Må ikke brukes hvis primæremballasjen allerede har blitt åpnet eller er skadet.



#### N FORSIKTIG: For å redusere risikoen for termiske skader, hypertermi eller hypotermi:

- 3M anbefaler kontinuerlig overvåking av kjernetemperatur. Dersom det ikke blir gjennomført kontinuerlig overvåking, skal temperaturen til pasienter som er ute av stand til å reagere, kommunisere og/eller som ikke kan føle temperatur, kontrolleres minst hvert 15. minutt, eller i henhold til institusjonens protokoll.
- Kontroller hudreaksjoner hos pasienter som er ute av stand til å reagere, kommunisere og/eller som ikke kan føle temperatur minst hvert 15. minutt, eller i henhold til institusjonens protokoll.
- Juster lufttemperaturen eller avbryt behandlingen når det terapeutiske målet er nådd, hvis forhøyede temperaturer

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hudreaksjoner i området som blir oppvarmet.

#### Instruksjoner

- Plasser den perforerte siden av 3M™ Bair Hugger™ varmeteppet (siden med små hull) rett oppå pasienten i kontakt med pasientens hud (figur A).
- Der det er aktuelt, kan dekkpapiret på tapestripen fjernes og varmeteppet kan festes til pasienten (figur B). Dette hindrer at luft kommer til inngrepsstedet.

Valgfritt: Plasser ett teppe eller laken oppå varmeteppet for å øke effektiviteten.



Advarsel: Ikke plasser en pasientfesteanordning (dvs. sikkerhetstropp eller tape) over varmeteppet.



Advarsel: Ikke legg varmeteppet direkte over et dispersivt elektrodeplaster.

Sett enden av slangen til Bair Hugger-varmeenheten inn i slangeporten (figur C). Vri den på plass for å sikre at den sitter tett. Et synlig merke er plassert rundt midtpartiet av slangeenden som en veiledning for hvor dypt inn slangen skal sitte. Støtt slangen for å sikre at den sitter godt fast.



Advarsel: Ikke behandle pasienter kun med slangen til varmeenheten. Fest alltid slangen til et Bair Hugger-varmeteppe før du gir varmebehandling.

#### MERK: Se spesielle hensyn for Bair Hugger-tepper nedenfor.

Velg ønsket temperaturinnstilling på varmeenheten for å starte varmebehandlingen. (Se brukerhåndboken for den aktuelle varmeenhetsmodellen)



Forsiktig: Anbefalinger for pasientovervåking:

- 3M anbefaler kontinuerlig overvåking av kjernetemperatur. Dersom det ikke blir gjennomført kontinuerlig overvåking, skal temperaturen til pasienter som er ute av stand til å reagere, kommunisere og/eller som ikke kan føle temperatur, kontrolleres minst hvert 15. minutt, eller i henhold til institusjonens protokoll.
- Kontroller hudreaksjoner hos pasienter som er ute av stand til å reagere, kommunisere og/eller som ikke kan føle temperatur minst hvert 15. minutt, eller i henhold til institusjonens protokoll.
- Juster lufttemperaturen eller avbryt behandlingen når det terapeutiske målet

## blir registrert, eller hvis det er en negativ hudreaksjoner i området som blir oppvarmet.

Avhengig av hvilken varmeenhetsmodell som benyttes, skal enheten slås av eller settes i standby-modus for å avbryte varmebehandlingen. Koble varmeenhetens slange fra varmeteppet og kast teppet iht. sykehusets retningslinjer.

#### Spesielle hensyn:

To porter for modell 54200 Torsoteppe med to porter, 52200/52301 Overkroppstepper og 57000 Tepper med operasjonstilgang

Det er to slangeporter, avhengig av hvilken klinikeren foretrekker. Sett det avtakbare slangeportkortet i slangeporten som ikke blir brukt under varmebehandlingen (figur D).

#### Hodeoppdekkingen for modellene 54000/54200 Torsotepper, 52200/52301 Overkroppstepper og 57000 Tepper med operasjonstilgang

Hvis pasienten er intubert og ventilert, kan hodeoppdekkingen legges over pasientens hode og hals (figur E). Hvis ikke skal hodeoppdekkingen skyves mellom kanalene i varmeteppet, borte fra pasientens hode.



Advarsel: Ikke la varmeteppet eller hodeoppdekkingen dekke pasientens hode eller luftveier når pasienten ikke blir mekanisk ventilert.

#### Modellene 52200/52301 Overkroppstepper (valgfritt)

Trekk ut knyttebåndene, som er sentrerte langs øvre og nedre kant av varmeteppet. Knytt disse båndene for å hindre at det oppblåste teppet letter fra pasienten. For å bruke overkroppsteppet med én armstøtte, kan halvparten av varmeteppet festes ved å feste tape rundt det eller ved å skyve det under pasienten (figur F).

#### Modellene 61000 Helkroppsteppe for operasjon og 31500 Flertilgangs postoperative tepper

For å bruke tilgangsflatene, kan den uklipte fliken på kanten av varmeteppet rives opp. Fjern dekkpapiret fra tapestripen på midten av teppet. Brett tilgangsflaten bakover og trykk den mot tapen. Trekk flaten av tapen for å løse den (figur G).

#### Modell 30500 Teppe med tilgang til bryst

Løft den gjennomsiktige plastoppdekkingen for å utføre pasientbehandling på overkroppen (figur H).

3M, Bair Hugger og Bair Hugger-logoen er varemerker for 3M.

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# ® KÄYTTÖOHJEET

#### Kävttöaiheet

3M<sup>™</sup> Bair Hugger<sup>™</sup> -lämpöhoitojärjestelmä on tarkoitettu hypotermian ehkäisyyn ja hoitoon. Sen lisäksi lämpöhoitojärjestelmää voi käyttää potilaalle miellyttävän lämpötilan aikaansaamiseen olosuhteissa, joissa potilaalla saattaa olla liian kuuma tai liian kylmä. Lämpöhoitojärjestelmää voidaan käyttää sekä aikuisilla että lapsilla.

- EI STERIILI.
- Yhdysvaltain liittovaltiolain mukaan tätä tuotetta saa myydä vain laillistetulle terveydenhuollon ammattilaiselle tai tällaisen henkilön määräyksestä.

#### Vasta-aiheet, varoitukset ja tärkeät huomautukset

### Huomiosanojen merkitykset



#### **VAROITUS:**

Merkitsee vaaratilannetta, joka saattaa johtaa kuolemaan tai vakavaan loukkaantumiseen, jos tilannetta ei vältetä.



#### TÄRKEÄ HUOMAUTUS:

Merkitsee vaaratilannetta, joka saattaa johtaa lievään tai kohtalaiseen loukkaantumiseen, jos tilannetta ei vältetä.



## NASTA-AIHE: Noudata seuraavia ohjeita palovammavaaran pienentämiseksi:

 Alaraajoja ei saa lämmittää aortan sulun aikana. Iskeemisten raajojen lämmittäminen voi aiheuttaa palovammoja.

#### NAROITUS: Noudata seuraavia ohjeita palovammavaaran pienentämiseksi:

- Potilaita ei saa lämmittää pelkästään Bair Hugger -lämpöpuhaltimen letkua käyttämällä. Yhdistä letku aina Bair Hugger -lämpöpeitteeseen ennen hoidon aloittamista.
- Älä anna potilaan maata lämpöpuhaltimen letkun päällä.
- Älä anna lämpöpuhaltimen letkun koskettaa suoraan potilaan ihoa lämmityksen aikana.
- Vastasyntyneitä, pikkulapsia, lapsia ja muita vaaralle alttiita potilaita ei saa jättää ilman valvontaa lämmityksen aikana.
- Potilaita, joiden verenkierto on huono, ei saa jättää ilman valvontaa pitkäkestoisten lämmitysjaksojen ajaksi.
- Älä aseta lämpöpeitteen rei'ittämätöntä puolta potilasta vasten. Aseta aina rei'itetty puoli suoraan potilaan ihoa vasten.
- Leikkaussalissa tätä lämpöpeitettä saa käyttää ainoastaan 500- tai 700-sarjan Bair Hugger -lämpöpuhaltimien kanssa.
- Leikkaussalissa ei saa käyttää 200-sarjan Bair Hugger -lämpöpuhallinta.
- Älä käytä Bair Hugger 800 -sarjan potilaansäädettävää lämpöpuhallinta minkään Bair Hugger -lämpöpeitteen kanssa.
- Älä jatka lämmityshoitoa, jos ylikuumenemisesta ilmoittava punainen Over temp -merkkivalo syttyy ja kuuluu hälytysääni.

## 0:15-mdx021666mJNEpiDrTsSstajDQC. 91/2-VaroitTsledail.0/03/all/7ittäPage 241 yhteys valtuutettuun huoltoteknikkoon.

- Älä aseta potilaan kiinnitysvälineitä (kuten turvahihnaa tai -teippiä) lämpöpeitteen päälle.
- Älä aseta lämpöpeitettä suoraan dispersiivisen elektrodityynyn päälle.
- NAROITUS: Noudata seuraavaa ohjetta lääkeaineiden muuttuneesta annostelusta aiheutuvan potilaan loukkaantumis- tai kuolemanvaaran pienentämiseksi:

 Lämpöpeitettä ei saa käyttää ihon läpi annettavan lääkityksen päällä.



#### ∖ VAROITUS: Noudata seuraavaa ohjetta ventilaatiohäiriöistä aiheutuvan loukkaantumisvaaran pienentämiseksi:

 Huolehdi, että lämpö- tai pääpeite ei peitä potilaan päätä tai hengitysteitä, kun potilasta ei ventiloida mekaanisesti.



#### /N VAROITUS: Noudata seuraavaa ohjetta potilaan putoamisesta aiheutuvan loukkaantumisvaaran pienentämiseksi:

 Älä käytä lämpöpeitettä potilaan siirtämiseen tai liikuttamiseen.



#### ↑ TÄRKEÄ HUOMAUTUS: Noudata seuraavaa ohjetta ristikontaminaatiovaaran pienentämiseksi:

Tämä lämpöpeite ei ole steriili ja on tarkoitettu AINOASTAAN potilaskohtaiseen käyttöön. Lakanan asettaminen lämpöpeitteen ja potilaan väliin ei estä tuotteen kontaminoitumista.



#### ⚠ TÄRKEÄ HUOMAUTUS: Noudata seuraavaa ohjetta tulipalovaaran pienentämiseksi:

Tuoteturvallisuuskomission syttymisherkistä kankaista antaman säännöksen 16 CFR 1610 mukaan tämä tuote kuuluu luokkaan I eli on syttymisherkkyydeltään normaali. Noudata suuritehoisten lämpölähteiden käytössä normaaleja turvallisuuskäytäntöjä.



### ∖ TÄRKEÄ HUOMAUTUS: Noudata seuraavia ohjeita palovammavaaran pienentämiseksi:

 Ei saa käyttää, jos myyntipakkaus on avattu aiemmin tai vaurioitunut.



#### ∖ TÄRKEÄ HUOMAUTUS: Noudata seuraavia ohjeita palovamma-, hypertermia- ja hypotermiavaaran pienentämiseksi:

- 3M suosittelee potilaan ydinlämmön jatkuvaa valvontaa. Jos jatkuvaa valvontaa ei tehdä, valvo vähintään 15 minuutin välein tai sairaalan käytännön mukaisesti sellaisten potilaiden lämpötilaa, jotka eivät pysty reagoimaan, kommunikoimaan ja/tai jotka ovat menettäneet tuntoaistinsa.
- Valvo vähintään 15 minuutin välein tai sairaalan käytännön mukaisesti sellaisten potilaiden ihovastetta, jotka eivät pysty reagoimaan, kommunikoimaan ja/tai jotka ovat menettäneet tuntoaistinsa.
- Säädä ilman lämpötilaa tai lopeta hoito, kun hoitotavoite on saavutettu, jos mittarit havaitsevat kohonneita lämpötiloja tai jos lämmitetyllä alueella ilmenee haitallinen ihovaste.

### Ohjeet

- Aseta 3M™ Bair Hugger™ -lämpöpeitteen rei'itetty puoli potilaan päälle suoraan ihoa vasten (kuva A).
- Poista tarvittaessa taustaosa tarraliuskasta ja kiinnitä lämpöpeite potilaaseen (kuva B). Tämä estää ilmaa virtaamasta kohti leikkausaluetta.

Vaihtoehto: Lisää lämmitystehoa asettamalla yksi kangaspeite tai lakana lämpöpeitteen päälle.



Varoitus: Älä aseta potilaan kiinnitysvälineitä (kuten turvahihnaa tai -teippiä) lämpöpeitteen päälle.



Varoitus: Älä aseta lämpöpeitettä suoraan dispersiivisen elektrodityynyn päälle.

Työnnä Bair Hugger -lämpöpuhaltimen letkun pää letkuporttiin (kuva C). Varmista letkua kiertämällä, että se kiinnittyy tiukasti. Letkun pään keskellä on merkki, joka osoittaa letkun asennussyvyyden. Varmista kunnollinen kiinnitys tukemalla letkua.

pelkästään lämpöpuhaltimen letkua käyttämällä. Yhdistä letku aina Bair Hugger -lämpöpeitteeseen ennen hoidon aloittamista.

**HUOMAUTUS:** Tutustu alla esitettyihin erityisesti huomioon otettaviin seikkoihin, jotka koskevat Bair Hugger -lämpöpeitteitä.

Aloita lämpöhoito valitsemalla tarvittava lämpötila-asetus lämmitysyksiköstä. (Katso käyttöoppaasta oman lämmitysyksikkösi malli.)



#### Tärkeä huomautus: Potilaan valvontaa koskevat suositukset:

- 3M suosittelee potilaan vdinlämmön. jatkuvaa valvontaa. Jos jatkuvaa valvontaa ei tehdä, valvo vähintään 15 minuutin välein tai sairaalan käytännön mukaisesti sellaisten potilaiden lämpötilaa, jotka eivät pysty reagoimaan, kommunikoimaan ja/tai jotka ovat menettäneet tuntoaistinsa.
- Valvo vähintään 15 minuutin välein tai sairaalan käytännön mukaisesti sellaisten potilaiden ihovastetta, jotka eivät pysty reagoimaan, kommunikoimaan ja/tai jotka ovat menettäneet tuntoaistinsa.
- Säädä ilman lämpötilaa tai lopeta hoito, kun hoitotavoite on saavutettu, jos mittarit havaitsevat kohonneita lämpötiloja tai jos lämmitetyllä alueella ilmenee haitallinen ihovaste.
- 5. Keskeytä lämpöhoito sammuttamalla lämpöpuhallin tai kytkemällä se valmiustilaan sen mukaan, mikä lämpöpuhallinmalli on käytössä. Irrota lämpöpuhaltimen letku lämpöpeitteestä ja hävitä peite sairaalan käytäntöjen mukaisesti.

#### Eritvisiä huomioon otettavia seikkoia:

Kaksi porttia mallin 54200 kaksiporttisissa torsopeitteissä, 52200/52301-mallisissa ylävartalopeitteissä ja 57000-mallisissa kirurgiseen käyttöön tarkoitetuissa peitteissä

Peitteissä on kaksi letkuporttia, joista lääkäri voi valita haluamansa. Aseta irrotettava letkuporttipahvi letkuporttiin, jota ei käytetä lämpöhoidon aikana (kuva D).

#### Pääpeite mallien 54000/54200 torsopeitteissä, 52200/52301-mallisissa ylävartalopeitteissä ja 57000-mallisissa kirurgiseen käyttöön tarkoitetuissa peitteissä

Jos potilas on intuboitu ja häntä ventiloidaan, niin aseta pääpeite potilaan pään ja kaulan päälle (kuva E). Muussa tapauksessa taita pääpeite lämpöpeitteen kanavien väliin, pois potilaan pään päältä.



Varoitus: Huolehdi, että lämpö- tai pääpeite ei peitä potilaan päätä tai hengitysteitä, kun potilasta ei ventiloida mekaanisesti.

#### Mallien

## 52200/52301 ylävartalopeitteet (valinnainen)

Vedä lämpöpeitteen ylä- ja alareunassa keskellä olevista kiinnitysnauhojen kielekkeistä. Sido nämä nauhat, jotta puhallusilma ei pääse nostamaan peitettä pois potilaan päältä. Kun ylävartalopeitteen . kanssa on tarpeen käyttää yhtä käsitukea, lämpöpeitteen toinen puoli voidaan sitoa kiertämällä teippiä sen ympärille tai taittamalla se potilaan alle (kuva F).

Mallin 61000 kirurgiseen käyttöön tarkoitetut kokovartalopeitteet ja mallin 31500 useita avattavia luukkuja sisältävät postoperatiiviset peitteet

Jos haluat käyttää luukkuja, repäise lämpöpeitteen reunassa olevaa leikkaamatonta kielekettä. Irrota peitteen keskellä olevan tarraliuskan taustapaperi. . Taita luukku taakse ja paina vasten tarraliuskaa. Irrota luukku vetämällä sitä poispäin tarraliuskasta (kuva G).

#### Mallin 30500 rintakehän näkyviin jättävä peite

Nosta läpinäkyvä muovipeite ylös, kun hoito kohdistuu potilaan ylävartalon alueelle (kuva H).

3M, Bair Hugger ja Bair Hugger -logo ovat 3M:n tavaramerkkejä.

Kanadassa tuotteen käyttö on luvanvaraista.

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#### Indicações de Uso

O Sistema de Gestão de Temperatura 3M™ Bair Hugger™ foi concebido para prevenir e tratar a hipotermia. Além disso, o sistema de gestão de temperatura pode ser utilizado para oferecer conforto térmico ao paciente quando, de acordo com as condições, ele possa sentir muito frio ou muito calor. O sistema de gestão de temperatura pode ser utilizado em pacientes adultos ou pediátricos.

- NÃO ESTÉRIL
- A Lei Federal (EUA) restringe a venda deste dispositivo à classe médica ou sob sua indicação.

## Contraindicações, Advertências e Precauções

#### Explicação das consequências das palavras de sinalização



# ADVERTÊNCIA:

Indica uma situação potencialmente perigosa que, se não for evitada, poderá resultar em óbito ou lesões graves.



#### PRECAUÇÃO:

Indica uma situação potencialmente perigosa que, se não for evitada, poderá resultar em lesões leves ou moderadas.

#### CONTRAINDICAÇÃO: Para reduzir o risco de lesões térmicas:

 Não aplique calor às extremidades inferiores durante a oclusão da aorta. Aplicar calor em membros isquémicos pode causar lesão térmica.



#### ADVERTÊNCIA: Para reduzir o risco de lesões térmicas:

- Não utilize o tubo da unidade de aquecimento diretamente no paciente. Conecte sempre o tubo a uma manta térmica Bair Hugger antes de aplicar o calor.
- Não permita que o paciente se deite sobre o tubo da unidade de aquecimento.
- Durante a aplicação, não permita o contato do tubo de aquecimento diretamente com a pele do paciente.
- Durante a aplicação, não deixe recém-nascidos, latentes, crianças e quaisquer outros pacientes vulneráveis sem supervisão.
- Não deixe pacientes com má perfusão sem monitorização durante aaplicação prolongada.
- Não coloque em contacto com o paciente o lado não perfurado da manta térmica. Coloque sempre o lado perfurado (contendo os pequenos orifícios) em contato com a pele do paciente.
- Na sala de operações, não utilize esta manta térmica com nenhum outro equipamento que não seja uma unidade de aquecimento Bair Hugger séries 500 ou 700.
- Não utilize uma unidade de aquecimento Bair Hugger série 200 na sala de operações.
- Não utilize a unidade de aquecimento controlada pelo paciente Bair Hugger série 800 com nenhuma manta térmica Bair Hugger.
- Não prossiga com a aplicação se a luz vermelha do indicador Over-temp acender ou se disparar o alarme sonoro. Desligue a unidade de aquecimento e contacte a assistência técnica autorizada.
- Não posicione o dispositivo de fixação (i.e. tira de contenção) por cima da manta térmica.
- Não posicione a manta térmica diretamente sobre eletrodos dispersivos.

#### ∖ ADVERTÊNCIA: Para reduzir o risco de danos ao paciente ou óbito devido a administração errónea de medicamentos:

 Não utilize a manta térmica por cima de medicamentos transdérmicos adesivos.



#### ADVERTÊNCIA: Para reduzir o risco de danos devido à interferência na ventilação:

 Quando o paciente não estiver sob ventilação mecânica, não permita que a manta térmica ou a cobertura plástica de aquecimento cubram o paciente na cabeça ou o fluxo de ar.

### 🕂 ADVERTÊNCIA: Para reduzir o risco de danos devido a quedas:

• Não utilize a manta térmica para transferir nem mover o paciente.

## M PRECAUÇÃO:

 Esta manta térmica não é estéril e foi concebida para uso ÚNICO. A colocação de um lençol entre a manta térmica e o paciente não evita a contaminação do produto.



#### PRECAUÇÃO: Para reduzir o risco de incêndio:

 Este produto é classificado como Classe I -Inflamabilidade Regular, conforme definido pela Comissão de Segurança de Produtos ao Consumidor na regulamentação de inflamabilidade de tecidos, 16 CFR 1610. Siga os protocolos de segurança padrão ao utilizar fontes de calor de alta intensidade.



#### PRECAUÇÃO: Para reduzir o risco de lesões térmicas:

 Não utilize se a embalagem já tiver sido aberta anteriormente ou se estiver danificada.



#### PRECAUÇÃO: Para reduzir o risco de lesões térmicas, hipertermia ou hipotermia:

- A 3M recomenda a monitorização contínua da temperatura central. Em caso de monitorização não contínua, monitorize a temperatura dos pacientes incapazes de reagir ou de comunicar e/ ou pacientes sem sensibilidade térmica a cada 15 minutos no mínimo ou conforme o protocolo institucional.
- Monitorize as respostas cutâneas de pacientes incapazes de reagir ou de comunicar e/ou pacientes sem sensibilidade térmica a cada 15 minutos no mínimo ou conforme o protocolo institucional.
- Ajuste a temperatura do ar ou interrompa a aplicação quando o objetivo terapêutico for atingido, ou em casos de elevação da temperatura ou reação cutânea adversa na área aquecida.

## Instruções

- Coloque o lado perfurado da manta térmica 3M™ Bair Hugger™ (contendo os pequenos orifícios) voltado para o paciente em contato com a pele (Figura A).
- Se for o caso, remova a tira da fita adesiva e fixe a manta térmica no paciente (Figura B). Isto evita que o ar passe para o local cirúrgico.

Opcional: Para aumentar a eficácia, coloque um cobertor ou um lençol sobre a manta térmica.



## Advertência: Não posicione o dispositivo de fixação (i.e. tira de contenção) por cima da

manta térmica. Advertência: Não posicione a manta térmica diretamente sobre eletrodos dispersivos.

Insira a extremidade do tubo da unidade de aquecimento na porta de entrada (Figura C). Faça um movimento de torção para garantir um encaixe adequado. Existe um marcador visual em torno da secção média da extremidade do tubo para guiar a profundidade da inserção. Apoie a tubuladura para garantir um encaixe seguro.

Advertência: Não utilize a tubuladura da unidade de aquecimento diretamente no paciente. Conecte sempre o tubo a uma manta térmica Bair Hugger antes de aplicar o calor.

#### OBSERVAÇÃO: Veja abaixo as considerações especiais para as mantas Bair Hugger.

Selecione a temperatura desejada na unidade de aquecimento para iniciar a aplicação terapêutica de calor. (Veja o Manuel do Usuário para o seu modelo específico de Unidade de Aquecimento)



### Precaução: Recomendações de Monitorização dos Pacientes

 A 3M recomenda a monitorização contínua da temperatura central. Em caso de monitorização não contínua, monitorize a temperatura dos pacientes incapazes de reagir ou de comunicar e/ ou pacientes sem sensibilidade térmica a

## protocolo institucional.

- Monitorize as respostas cutâneas de pacientes incapazes de reagir ou de comunicar e/ou pacientes sem sensibilidade térmica a cada 15 minutos no mínimo ou conforme o protocolo institucional.
- Ajuste a temperatura do ar ou interrompa a aplicação quando o objetivo terapêutico for atingido, ou em casos de elevação da temperatura ou reação cutânea adversa na área aquecida.
- Dependendo da unidade de aquecimento 5. utilizada, desligue ou coloque em modo de espera para interromper a aplicação de calor. Desconecte ao tubuladura da unidade de aquecimento da manta e descarte-a de acordo com a política hospitalar.

#### Considerações especiais

Dupla Entrada para Manta para Tronco Modelo 54200, Mantas para Parte Superior do Corpo 52200/52301 e Manta para Acesso Cirúraico 57000

Há duas portas de entrada do tubo conforme preferência do corpo clínico. Coloque a tampa removível da porta de entrada que não está a ser utilizada durante a aplicação de calor (Figura D).

Cobertura Plástica de Aquecimento para os Modelos: Mantas para Tronco 54000/54200, Mantas para Parte Superior do Corpo 52200/52301 e Manta para Acesso Cirúrgico 57000.

Se o paciente for entubado e ventilado, coloque a cobertura plástica de aquecimento por cima da guarde-a entre os canais da manta térmica, longe da cabeça do paciente.

Advertência: Quando o paciente não estiver sob ventilação mecânica, não permita que a manta térmica ou a cobertura plástica de aquecimento cubram o paciente na cabeça ou o fluxo de ar.

#### Mantas para a Parte Superior do Corpo Modelos 52200/52301 (Opcional)

Puxe as tiras localizadas ao longo das extremidades superior e inferior da manta térmica. Fixe as tiras para impedir que a manta insuflada flutue sobre o paciente. Para utilizar a manta para a parte superior do corpo numa tala de braço, uma metade da manta térmica pode ser fixa, enrolando a fita em torno dela, ou dobrando-a por baixo do paciente (Figura F)

#### Modelos: Manta Cirúrgica Corpo Inteiro 61000 e Manta Pós-Operatória Múltiplo Acesso 31500

Para usar os painéis de acesso, retire a aba na extremidade da manta térmica. Remova a proteção da fita adesiva localizada no centro da manta. Dobre de volta o painel de acesso e pressione-o contra a fita adesiva. Puxe o painel da fita para soltá-lo (Figura G).

#### Manta de Acesso ao Tórax Modelo 30500

Levante a cobertura plástica para prestar cuidados à parte superior do corpo do paciente (Figura H).

3M, Bair Hugger e o logotipo Bair Hugger são marcas comerciais da 3M.

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#### Ενδείξεις χρήσης

To 3M™ Bair Hugger™ Σύστημα Διαχείρισης Θερμοκρασίας χρησιμοποιείται για την αποφυγή και την αντιμετώπιση της υποθερμίας. Επιπλέον, το σύστημα διαχείρισης θερμοκρασίας μπορεί να χρησιμοποιηθεί για να παρέχει επαρκή θερμότητα στους ασθενείς όταν υφίστανται συνθήκες που ενδέχεται να προκαλέσουν υπερβολική αύξηση ή μείωση της θερμοκρασίας του σώματος των ασθενών. Το σύστημα διαχείρισης θερμοκρασίας μπορεί να χρησιμοποιηθεί σε ενήλικους και παιδιατρικούς ασθενείς.

- ΜΗ ΑΠΟΣΤΕΙΡΩΜΕΝΟ.
- Η ομοσπονδιακή νομοθεσία (Η.Π.Α.) περιορίζει την πώληση αυτής της συσκευής μόνο από ή κατόπιν εντολής αδειούχου επαγγελματία του τομέα υγειονομικής περίθαλψης.

#### Αντενδείξεις, προειδοποιήσεις και προφυλάξεις

#### Ερμηνεία των συνεπειών των προειδοποιητικών λέξεων



#### ΠΡΟΕΙΔΟΠΟΙΗΣΗ:

Υποδεικνύει μια επικίνδυνη κατάσταση η οποία, εάν δεν αποφευχθεί, ενδέχεται να έχει ως αποτέλεσμα τον θάνατο ή τον σοβαρό τραυματισμό.



#### ΠΡΟΣΟΧΗ:

Υποδεικνύει μια επικίνδυνη κατάσταση η οποία, εάν δεν αποφευχθεί, ενδέχεται να προκαλέσει ελαφρύ ή μέτριο τραυματισμό.



#### ΑΝΤΕΝΔΕΙΞΗ: Για τη μείωση του κινδύνου θερμικού τραυματισμού:

Μην εφαρμόζετε θερμότητα στα κάτω άκρα κατά τη διάρκεια αποκλεισμού (cross-clamping) της αορτής. Μπορεί να προκληθεί θερμικός τραυματισμός εάν εφαρμοστεί θερμότητα σε ισχαιμικά άκρα.

#### **ΠΡΟΕΙΔΟΠΟΙΗΣΗ: Για τη μείωση του κινδύνου** θερμικού τραυματισμού:

- Μην παρέχετε θεραπεία στους ασθενείς μόνο με τον εύκαμπτο σωλήνα της μονάδας θέρμανσης Bair Hugger. Συνδέετε πάντα τον εύκαμπτο σωλήνα σε μια κουβέρτα θέρμανσης Bair Hugger πριν χορηγήσετε θεραπεία θέρμανσης.
- Μην αφήνετε τον ασθενή να ξαπλώσει επάνω στον εύκαμπτο σωλήνα της μονάδας θέρμανσης.
- Μην αφήνετε τον εύκαμπτο σωλήνα της μονάδας θέρμανσης να έρχεται σε άμεση

- επαφή με το δέρμα του ασθενούς κατά τη διάρκεια της θεραπείας με θέρμανση.
- Μην αφήνετε νεογνά, βρέφη, παιδιά και άλλους ευάλωτους πληθυσμούς ασθενών ανεπιτήρητους κατά τη διάρκεια της θεραπείας με θέρμανση.
- Μην αφήνετε ασθενείς με πτωχή αιμάτωση ανεπιτήρητους κατά τη διάρκεια παρατεταμένης θεραπείας θέρμανσης.
- Μην τοποθετείτε τη μη διάτρητη πλευρά της κουβέρτας θέρμανσης επάνω στον ασθενή. Τοποθετείτε πάντα τη διάτρητη πλευρά (με τις μικρές οπές) απευθείας επάνω στον ασθενή σε επαφή με το δέρμα του ασθενούς.
- Στο χειρουργείο, μη χρησιμοποιείτε αυτήν τη κουβέρτα θέρμανσης με οποιαδήποτε άλλη συσκευή εκτός από μια μονάδα θέρμανσης Bair Hugger σειράς 500 ή 700.
- Μη χρησιμοποιείτε μια μονάδα θέρμανσης Bair Hugger σειράς 200 στο χειρουργείο.
- Μη χρησιμοποιείτε μια ρυθμιζόμενη μονάδα θέρμανσης ασθενούς Bair Hugger σειράς 800 με οποιαδήποτε Κουβέρτα Θέρμανσης . Bair Hugger.
- Μη συνεχίζετε τη θεραπεία θέρμανσης εάν ανάψει η κόκκινη ενδεικτική λυχνία υπερθέρμανσης και ακουστεί ο ηχητικός συναγερμός. Αποσυνδέστε το φις της μονάδας θέρμανσης και επικοινωνήστε με έναν ειδικευμένο τεχνικό σέρβις.
- Μην τοποθετείτε ένα μέσο συγκράτησης (δηλ. ιμάντα ή ταινία ασφαλείας) επάνω από τη κουβέρτα θέρμασης του ασθενούς.
- Μην τοποθετείτε τη κουβέρτα θέρμανσης ακριβώς επάνω από ένα ηλεκτρόδιο διασποράς.

#### ΠΡΟΕΙΔΟΠΟΙΗΣΗ: Για να μειώσετε τον κίνδυνο τραυματισμού του ασθενούς ή θανάτου λόγω αλλαγής στη χορήγηση φαρμάκου:

Μη χρησιμοποιείτε κουβέρτα θέρμανσης επάνω από έμπλαστρα διαδερμικής χορήγησης φαρμάκου.



# ⚠ ΠΡΟΕΙΔΟΠΟΙΗΣΗ. Για τη μείωση του κινδύνου τραυματισμού λόγω παρεμπόδισης του αερισμού:

Μην αφήνετε τη κουβέρτα θέρμανσης ή το κάλυμμα κεφαλιού να καλύπτει το κεφάλι ή τον αεραγωγό του ασθενούς όταν ο ασθενής δεν υποβάλλεται σε μηχανική αναπνευστική υποστήριξη.



ΠΡΟΕΙΔΟΠΟΙΗΣΗ: Για τη μείωση της πιθανότητας τραυματισμού λόγω πτώσης του ασθενούς:

# 0:15-md-02666 είτε ΝΕρερα θέρρανος Ο. . 912-1 μο Τρίμε συν είνου τελ Ρμασίας 244 να μετακέρετε ή να μετακινήσετε τον ασθενή.

να μεταφέρετε ή να μετακινήσετε τον ασθενή.



#### ΤΡΟΣΟΧΗ: Για τη μείωση του κινδύνου διασταυρούμενης μόλυνσης:

Αυτή η κουβέρτα θέρμανσης δεν είναι αποστειρωμένη και προορίζεται για χρήση ΜΟΝΟ σε έναν ασθενή. Η τοποθέτηση σεντονιού μεταξύ της κουβέρτας θέρμανσης και του ασθενούς δεν αποτρέπει τη μόλυνση του προϊόντος.



#### 🔪 ΠΡΟΣΟΧΗ: Για τη μείωση του κινδύνου πυρκαγιάς:

Αυτό το προϊόν είναι ταξινομημένο ως Κατηγορίας Ι – Κανονικής Ευφλεκτότητας, όπως ορίζεται από τον κανονισμό για τα εύφλεκτα υφάσματα της Επιτροπής Ασφάλειας των Καταναλωτικών Προϊόντων, 16 CFR 1610. Ακολουθείτε τα τυπικά πρωτόκολλα ασφάλειας όταν χρησιμοποιείτε πηγές θερμότητας υψηλής έντασης.



#### 📐 ΠΡΟΣΟΧΗ: Για τη μείωση του κινδύνου θερμικού τραυματισμού:

 Μη χρησιμοποιείτε το προϊόν αν η πρωτογενής συσκευασία έχει προηγουμένως ανοιχθεί ή υποστεί ζημιά.



#### **ΤΡΟΣΟΧΗ: Για τη μείωση του κινδύνου** θερμικού τραυματισμού, υπερθερμίας ή υποθερμίας:

- Η 3Μ συνιστά τη συνεχή παρακολούθηση της θερμοκρασίας πυρήνα. Σε απουσία συνεχούς παρακολούθησης, παρακολουθείτε τη θερμοκρασία των ασθενών που δεν είναι ίκανοι να αντιδράσουν, να επικοινωνήσουν ή/ και οι οποίοι δεν μπορούν να αισθανθούν τη θερμοκρασία, τουλάχιστον κάθε 15 λεπτά ή σύμφωνα με το πρωτόκολλο του νοσοκομείου.
- Παρακολουθείτε τις δερματικές αντιδράσεις των ασθενών που δεν είναι ίκανοι να αντιδράσουν, να επικοινωνήσουν ή/και οι οποίοι δεν μπορούν να αισθανθούν τη θερμοκρασία, τουλάχιστον κάθε 15 λεπτά ή σύμφωνα με το πρωτόκολλο του νοσοκομείου.
- Προσαρμόστε τη θερμοκρασία του αέρα του περιβάλλοντος ή διακόψτε την θεραπεία όταν επιτευχθεί ο θεραπευτικός στόχος, εάν καταγραφούν αυξημένες θερμοκρασίες ή εάν υπάρχει ανεπιθύμητη δερματική αντίδραση στη θερμαινόμενη περιοχή.

#### Οδηγίες

- Τοποθετήστε τη διάτρητη πλευρά της κουβέρτας θέρμανσης 3Μ™ Bair Hugger™ (την πλευρά με τις μικρές οπές) απευθείας επάνω στον ασθενή σε επαφή με το δέρμα του ασθενούς (Εικόνα Α)
- Όπου εφαρμόζεται, αφαιρέστε το προστατευτικό στρώμα από την αυτοκόλλητη ταινία και κολλήστε τη κουβέρτα θέρμανσης στον ασθενή (Εικόνα Β). Αυτό εμποδίζει τη ροή του αέρα προς το χειρουργικό πεδίο.

**Προαιρετικά:** Τοποθετήστε μια υφασμάτινη κουβέρτα ή σεντόνι επάνω από τη κουβέρτα θέρμανσης για να αυξήσετε την αποτελεσματικότητα.



**Προειδοποίηση:** Μην τοποθετείτε ένα μέσο συγκράτησης (δηλ. ιμάντα ή ταινία ασφαλείας) επάνω από τη κουβέρτα θέρμασης του ασθενούς.



**Προειδοποίηση:** Μην τοποθετείτε τη κουβέρτα θέρμανσης ακριβώς επάνω από ένα ηλεκτρόδιο διασποράς.

Εισάγετε το άκρο του εύκαμπτου σωλήνα της μονάδας θέρμανσης Bair Hugger εντός της θύρας εύκαμπτου σωλήνα (Εικόνα C). Χρησιμοποιήστε περιστροφική κίνηση για να διασφαλίσετε ότι υπάρχει καλή εφαρμογή. Ένας οπτικός δείκτης βρίσκεται γύρω από το μεσαίο τμήμα του άκρου του εύκαμπτου σωλήνα για την καθοδήγηση της εισαγωγής του εύκαμπτου σωλήνα. Υποστηρίξτε τον εύκαμπτο σωλήνα για να εξασφαλίσετε την ασφαλή προσάρτηση.



**!** Προειδοποίηση: Μην παρέχετε θεραπεία στους ασθενείς μόνο με τον εύκαμπτο σωλήνα της μονάδας θέρμανσης. Συνδέετε πάντα τον εύκαμπτο σωλήνα σε μια κουβέρτα θέρμανσης Bair Hugger πριν χορηγήσετε θεραπεία θέρμανσης.

#### ΣΗΜΕΙΩΣΗ: Ανατρέξτε στα ειδικά θέματα που πρέπει να λαμβάνονται υπόψη για τις κουβέρτες Bair Hugger που παρουσιάζονται παρακάτω.

Επιλέξτε την επιθυμητή ρύθμιση θερμοκρασίας στη μονάδα θέρμανσης για να ξεκινήσετε τη θεραπεία θέρμανσης, (Ανατρέξτε στο Εγχειρίδιο



- Η 3Μ συνιστά τη συνεχή παρακολούθηση της θερμοκρασίας πυρήνα. Σε απουσία συνεχούς παρακολούθησης, παρακολουθείτε τη θερμοκρασία των ασθενών που δεν είναι ίκανοι να αντιδράσουν, να επικοινωνήσουν ή/ και οι οποίοι δεν μπορούν να αισθανθούν τη θερμοκρασία, τουλάχιστον κάθε 15 λεπτά ή σύμφωνα με το πρωτόκολλο του νοσοκομείου.
- Παρακολουθείτε τις δερματικές αντιδράσεις των ασθενών που δεν είναι ίκανοι να αντιδράσουν, να επικοινωνήσουν ή/και οι οποίοι δεν μπορούν να αισθανθούν τη θερμοκρασία, τουλάχιστον κάθε 15 λεπτά ή σύμφωνα με το πρωτόκολλο του νοσοκομείου.
- Προσαρμόστε τη θερμοκρασία του αέρα του περιβάλλοντος ή διακόψτε την θεραπεία όταν επιτευχθεί ο θεραπευτικός στόχος, εάν καταγραφούν αυξημένες θερμοκρασίες ή εάν υπάρχει ανεπιθύμητη δερματική αντίδραση στη θερμαινόμενη περιοχή.
- Με βάση το χρησιμοποιούμενο μοντέλο μονάδας θέρμανσης, απενεργοποιήστε τη μονάδα ή θέστε την σε κατάσταση αναμονής για να διακόψετε τη θεραπεία θέρμανσης. Αποσυνδέστε τον εύκαμπτο σωλήνα της μονάδας θέρμανσης από τη κουβέρτα θέρμανσης και απορρίψτε την κουβέρτα σύμφωνα με την πολιτική του νοσοκομείου.

### Ειδικά θέματα:

Διπλή θύρα για Κουβέρτα Κορμού Διπλής Θύρας Μοντέλο 54200, Κουβέρτες Ανώτερου Μέρου του Σώματος Μοντέλο 52200/52301, και Κουβέρτα Χειρουργικής Πρόσβασης 57000

Παρέχονται δύο θύρες εύκαμπτου σωλήνα για χρήση ανάλογα με την προτίμηση του χειρουργού. Τοποθετήστε την αφαιρέσιμη κάρτα θύρας εύκαμπτου σωλήνα στη θύρα εύκαμπτου σωλήνα που δεν χρησιμοποιείται κατά τη διάρκεια της θεραπείας θέρμανσης (Εικόνα D).

#### Κάλυμμα Κεφαλιού για Κουβέρτες Κορμού Μοντέλα 54000/54200, Κουβέρτες Ανώτερου Μέρους του Σώματος 52200/52301 και Κουβέρτες Χειρουργικής Πρόσβασης 57000

Εάν ένας ασθενής είναι διασωληνωμένος και υπό μηχανική αναπνευστική υποστήριξη, τοποθετήστε το . κάλυμμα κεφαλιού επάνω από το κεφάλι και τον λαιμό του ασθενούς (Εικόνα Ε), και διπλώστε το κάλυμμα μεταξύ των καναλιών της κουβέρτας θέρμανσης, μακριά από το κεφάλι του ασθενούς.



**Προειδοποίηση:** Μην αφήνετε τη κουβέρτα θέρμανσης ή το κάλυμμα κεφαλιού να καλύπτει το κεφάλι ή τον αεραγωγό του ασθενούς όταν ο ασθενής δεν υποβάλλεται σε μηχανική αναπνευστική υποστήριξη.

#### Μοντέλα 52200/52301 Κουβέρτες Ανώτερου Μέρους του Σώματος (Προαιρετικά)

Τραβήξτε τις λωρίδες πρόσδεσης, κεντραρισμένα κατά μήκος της επάνω και κάτω άκρης της κουβέρτας θέρμανσης. Προσδέστε αυτές τις λωρίδες για αποτρέψετε την ανύψωση της διογκωμένης κουβέρτας μακριά από τον ασθενή. Για να χρησιμοποιήσετε την κουβέρτα ανώ σώματος με ένα στήριγμα χεριού, το ένα ήμισυ της κουβέρτας θέρμανσης μπορεί να προσδεθεί τυλίγοντας ταινία γύρω από αυτό ή διπλώνοντάς το κάτω από τον ασθενή (Εικόνα F).

#### Μοντέλα 61000 Πλήρους Σώματος Χειρουργικές, και 31500 Μετεγχειρητικές Κουβέρτες Πολλαπλής Πρόσβασης

Για χρήση των πλαισίων πρόσβασης, σχίστε τα περιγεγραμμένα πλαίσια στην άκρη της κουβέρτας θέρμανσης. Αφαιρέστε το προστατευτικό στρώμα από την ταινία στο κέντρο της κουβέρτας. Διπλώστε το πλαίσιο πρόσβασης προς τα πίσω και πιέστε την εκτεθειμένη ταινία. Τραβήξτε το πλαίσιο μακριά από την ταινία για να το απελευθερώσετε (Εικόνα G).

#### Μοντέλο 30500 Κουβέρτα Θωρακικής Πρόσβασης

Ανασηκώστε το διαφανές πλαστικό κάλυμμα για να παρέχετε φροντίδα στον ασθενή στην ανώτερη περιοχή του σώματος (Εικόνα Η).

Τα 3M, Bair Hugger και το λογότυπο Bair Hugger είναι εμπορικά σήματα της 3Μ.

Χρησιμοποιείται κατόπιν αδείας στον Καναδά. © 2016, 3M. Με την επιφύλαξη παντός δικαιώματος.

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#### Wskazania do stosowania

System do terapii grzewczej 3M™ Bair Hugger™ służy do zapobiegania i leczenia hipotermii. System do terapii grzewczej dodatkowo można stosować w celu zapewnienia pacjentowi komfortu termicznego w warunkach mogących powodować uczucie gorąca lub chłodu u pacjenta. Systemu do terapii grzewczej można używać u pacjentów dorosłych i dzieci.

- PRODUKT NIFJAŁOWY.
- Prawo federalne (USA) ogranicza sprzedaż tego wyrobu do sprzedaży przez lub na zlecenie licencjonowanego pracownika służby zdrowia.

#### Przeciwwskazania, ostrzeżenia i uwagi

### Wyjaśnienie znaczenia słów ostrzegawczych



#### **OSTRZEŻENIE:**

Oznacza niebezpieczną sytuację, która — jeśli nie uda się jej zapobiec - może spowodować zgon lub poważne obrażenia.



### UWAGA:

Oznacza niebezpieczną sytuację, która — jeśli nie uda się jej zapobiec - może spowodować nieznaczne lub umiarkowane obrażenia.



#### PRZECIWWSKAZANIA: Aby ograniczyć ryzyko powstania obrażeń termicznych:

 Podczas poprzecznego zakleszczenia aorty nie należy ogrzewać kończyn dolnych. W razie ogrzania niedokrwionych kończyn może dojść do obrażeń termicznych.



#### **○ OSTRZEŻENIE: Aby ograniczyć ryzyko** powstania obrażeń termicznych:

- Pacjentów nie należy leczyć za pomocą samego węża grzewczego Aparatu do terapii grzewczej Bair Hugger. Przed rozpoczęciem terapii grzewczej wąż należy zawsze podłączyć do koca ogrzewającego Bair Hugger.
- Nie dopuścić, aby ciało pacjenta spoczywało na wężu aparatu do terapii grzewczej.
- Nie dopuścić, aby w trakcie podawania terapii grzewczej wąż aparatu do terapii grzewczej wchodził w bezpośredni kontakt ze skórą pacjenta.
- W czasie podawania terapii grzewczej nie należy pozostawiać bez nadzoru noworodków, niemowląt, dzieci ani innych wrażliwych pacjentów.
- W czasie dłużej trwającej terapii grzewczej nie pozostawiać pacjentów ze słabą perfuzją bez nadzoru.
- Nie kłaść na ciele pacjenta nieperforowanej strony koca ogrzewającego. Bezpośrednio na powierzchni ciała pacjenta, w bezpośrednim kontakcie ze skórą pacjenta należy zawsze umieszczać perforowaną stronę koca (z niewielkimi otworami).
- Na sali operacyjnej nie należy używać opisywanego koca ogrzewającego w połączeniu z jakimkolwiek urządzeniem innym niż Aparat do terapii grzewczej Bair Hugger serii 500 lub 700.
- Aparatu do terapii grzewczej Bair Hugger serii 200 nie należy używać na sali operacyjnej.
- Aparatu do terapii grzewczej pacjenta Bair Hugger serii 800 nie należy używać z żadnym kocem grzewczym Bair Hugger.
- Nie kontynuować stosowania terapii grzewczej, jeśli świeci się czerwona lampka wskaźnika przegrzania i rozlega się alarm dźwiękowy. Odłączyć aparat do terapii grzewczej od zasilania i skontaktować się z wykwalifikowanym technikiem serwisu.
- Na kocu ogrzewającym nie należy umieszczać żadnych urządzeń zabezpieczających ciało pacjenta (np. pasy lub taśmy bezpieczeństwa).
- Nie umieszczać koca ogrzewającego bezpośrednio na podkładce elektrody dyspersyjnej.



OSTRZEŻENIE: Aby obniżyć ryzyko obrażeń ciała lub zgonu pacjenta z powodu nieprawidłowego sposobu podania leku:

 Nie używać koca ogrzewającego na plastrach transdermalnych systemów podawania leku.

### OSTRZEŻENIE. Aby obniżyć ryzyko obrażeń ciała z powodu zakłóceń wentylacji:

 Nie dopuścić, aby koc ogrzewający lub serweta na głowę przykrywały głowę pacjenta lub jego drogi oddechowe, jeśli nie jest podłączony do wentylacji mechanicznej.

#### 🖍 OSTRZEŻENIE: Aby obniżyć ryzyko obrażeń ciała spowodowanych upadkiem pacjenta:

 Nie używać koca ogrzewającego do przenoszenia lub przesuwania ciała pacienta.

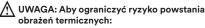
## M UWAGA: Aby obniżyć ryzyko związane ze zakażeniem krzyżowym:

 Koc ogrzewający nie jest jałowy i służy do zastosowania WYŁĄCZNIE u jednego pacjenta. Umieszczenie prześcieradła między kocem ogrzewającym a ciałem pacjenta nie zapobiega zanieczyszczeniu produktu.



## UWAGA: Aby ograniczyć ryzyko pożaru:

 Produkt został sklasyfikowany jako produkt klasy I o normalnym stopniu palności który określa rozporządzenie Komisji ds bezpieczeństwa produktów konsumenckich (ang. Consumer product Safety Commission) w sprawie materiałów łatwopalnych, 16 CFR 1610. Podczas stosowania źródeł ciepła o dużym natężeniu należy przestrzegać standardowych protokołów bezpieczeństwa.



 Nie używać, jeśli oryginalne opakowanie było wcześniej otwierane lub jest uszkodzone.

# UWAGA: Aby ograniczyć ryzyko powstania obrażeń termicznych, hipertermii lub hipotermii:

- Firma 3M zaleca ciągłe monitorowanie temperatury ciała. U pacjentów, u których występuje brak zdolności reakcji, komunikacji i/lub odczuwania temperatury w przypadku braku ciągłego monitorowania należy co najmniej co 15 minut lub zgodnie z protokołem ośrodka monitorować temperature ciała.
- U pacjentów, u których występuje brak zdolności reakcji, komunikacji i/lub odczuwania temperatury należy monitorować odpowiedź skórną co najmniej co 15 minut lub zgodnie z protokołem ośrodka monitorować temperaturę ciała.
- Po osiagnieciu celu terapeutycznego, w razie odnotowania zapisu podniesionej temperatury lub w przypadku niepożądanej odpowiedzi skórnej na ogrzewanym obszarze należy dostosować temperaturę lub zakończyć terapię.

#### Instrukcie

- Umieścić perforowaną stronę koca ogrzewającego 3M™ Bair Hugger™ (strona z niewielkimi otworami) bezpośrednio na powierzchni ciała pacjenta, zapewniając w bezpośredni kontakt ze skórą pacjenta (Rysunek A).
- W razie potrzeby usunąć tylną powłokę pasa taśmy samoprzylepnej i przykleić koc ocieplający do ciała pacjenta (Rysunek B). Zapobiega to napływowi powietrza do pola operacyjnego.

Opcjonalnie: Aby zwiększyć skuteczność działania koca ogrzewającego umieścić na jego powierzchni jeden koc lub prześcieradło z tkaniny.



Ostrzeżenie: Na kocu ogrzewającym nie należy umieszczać żadnych urządzeń zabezpieczających ciało pacjenta (np. pasy lub taśmy bezpieczeństwa).

Ostrzeżenie: Nie umieszczać koca ogrzewającego bezpośrednio na podkładce elektrody dyspersyjnej.

{0}Wprowadzić koniec węża aparatu do terapii grzewczej Bair Hugger do portu węża w kocu grzewczym (Rysunek C).{1} Aby zapewnić prawidłowe dopasowanie, należy zastosować ruch obrotowy. Wokół środkowej części końca węża znajduje się marker wizualny, który ułatwia

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Aby zapewnić bezpieczne dopasowanie, należy zapewnić podparcie weża.



Ostrzeżenie: Pacjentów nie należy leczyć za pomocą samego węża grzewczego aparatu do terapii grzewczej. Przed rozpoczęciem terapii grzewczej wąż należy zawsze podłączyć do koca ogrzewającego Bair Hugger.

#### UWAGA: Patrz poniższy opis uwag specjalnych dotyczących koców ogrzewających Bair Hugger.

Aby rozpocząć terapię grzewczą, należy wybrać właściwe ustawienie temperatury. (Patrz Podręcznik operatora konkretnego modelu aparatu do terapii grzewczej)



UWAGA: Zalecenia dotyczące monitorowania stanu pacjenta:

- Firma 3M zaleca ciągłe monitorowanie temperatury ciała. U pacjentów, u których występuje brak zdolności reakcji, komunikacji i/lub odczuwania temperatury, w przypadku braku ciągłego monitorowania należy co najmniej co 15 minut lub zgodnie z protokołem ośrodka monitorować temperaturę ciała.
- U pacjentów, u których występuje brak zdolności reakcji, komunikacji i/lub odczuwania temperatury należy monitorować odpowiedź skórną co najmniej co 15 minut lub zgodnie z protokołem ośrodka monitorować temperature ciała.
- Po osiągnięciu celu terapeutycznego, w razie odnotowania zapisu podniesionej temperatury lub w przypadku niepożądanej odpowiedzi skórnej na ogrzewanym obszarze należy dostosować temperaturę lub zakończyć terapię.
- W zależności od zastosowanego modelu aparatu do terapii grzewczej wyłączyć aparat lub uruchomić tryb uśpienia, aby zatrzymać terapię grzewczą. Odłączyć wąż aparatu do terapii grzewczej od koca ogrzewającego i zutylizować koc zgodnie z polityką szpitala.

### Uwagi specjalne:

Podwójny port modelu 54200 Koca na tułów z podwójnym portem, Koców na górną połowę

# chirurgiczny 57000

Do wyboru lekarza dostępne są dwa porty węża. Umieścić usuwalną kartę portu węża w porcie węża, który nie będzie używany podczas terapii grzewczej

Serweta na głowę do modeli 54000/54200 Koców na tułów, Koców na górną połowę ciała 52200/52301 i Koca zapewniającego dostęp chirurgiczny 57000

Jeśli pacjent jest intubowany i podłączony do wentylacji mechanicznej, na głowie i szyi pacjenta należy położyć serwetę (Rysunek E); lub też wsunąć serwetę między kanały koca ogrzewającego z dala od głowy pacjenta.



Ostrzeżenie: Nie dopuścić, aby koc ogrzewający lub serweta na głowę przykrywały głowę pacjenta lub jego drogi oddechowe, jeśli nie jest podłączony do wentylacji mechanicznej.

#### Modele 52200/52301 Koców na górną połowę ciała (opcjonalny)

Pociągnąć patki pasa łączącego wyśrodkowane wzdłuż górnych i dolnych krawędzi koca ogrzewającego. Połączyć pasy, aby zapobiec uniesieniu wypełnionego koca z ciała pacjenta. Aby użyć koca na górną połowę ciała z jednym ramieniem, jedną połowę koca ogrzewającego można odłączyć przez owinięcie wokół niego taśmy lub wsunięcie jej pod ciało pacjenta (Rysunek F).

#### Modele 61000 Koc chirurgiczny na cale ciało i 31500 Wielodostępowy koc pooperacyjny

Aby skorzystać z paneli dostępu, należy rozerwać nieobcięty znacznik przy krawędzi koca ogrzewającego. Usunąć tylną warstwę z paska taśmy na środkowej części koca. Zagiąć panel dostępu do tyłu i przycisnąć do odsłoniętej taśmy. Odciągnąć panel od taśmy, aby go zwolnić (Rysunek G).

#### Model 30500 Koca zapewniającego dostęp do klatki piersiowej

Podnieść przezroczystą plastikową serwetę, aby umożliwić działanie medyczne na obszarze górnej części ciała pacjenta (Rysunek H).

3M, Bair Hugger i logo Bair Hugger to znaki handlowe firmy 3M.

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# **HU HASZNÁLATI UTASÍTÁS**

#### Felhasználási javallatok

A 3M™ Bair Hugger™ hőmérséklet-szabályozó rendszer a hipotermia megelőzésére és kezelésére szolgál. Ezen felül a hőmérséklet-szabályozó rendszer segít a beteg hőkomfortjának biztosításában, ha a betegnek túl melege van, vagy nagyon fázik a környezeti feltételek miatt. A hőmérséklet-szabályozó rendszer felnőtt és gyermek betegek esetén is használható.

- Az Amerikai Egyesült Államok szövetségi törvényeinek értelmében ez az eszköz kizárólag engedéllyel rendelkező egészségügyi szakember által vagy elrendelésére értékesíthető.

#### Ellenjavallatok, figyelmeztetések és óvintézkedések

#### Jelzőszavak

## következményeinek magyarázata



#### FIGYELMEZTETÉS:

Olyan veszélyes helyzetet jelez, amely halálhoz vagy súlyos sérüléshez vezethet, ha nem kerülik el.



## VIGYÁZAT:

Olyan veszélyes helyzetet jelez, amely enyhe vagy közepesen súlyos sérüléshez vezethet, ha nem kerülik el.



#### ELLENJAVALLAT: A hő okozta sérülés kockázatának csökkentése érdekében:

 Aorta cross-clamping műtéte során ne melegítse az alsó végtagokat. Hő okozta sérülés léphet fel, ha melegíti az iszkémiás végtagokat.



#### FIGYELMEZTETÉS: A hő okozta sérülés kockázatának csökkentése érdekében:

 Önmagában a Bair Hugger melegítőegység gégecsövével ne kezelje a betegeket. A

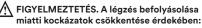
- gégecsövet mindig csatlakoztassa egy Bair Hugger melegítőtakaróhoz, mielőtt megkezdené a melegítő kezelést.
- Ne hagyja, hogy a melegítőegység gégecsöve a beteg alatt legyen.
- Ne hagyja, hogy a melegítőegység gégecsöve közvetlenül a beteg bőréhez érjen a melegítő kezelés alatt.
- Újszülötteket, csecsemőket, gyermekeket és más kiszolgáltatott betegeket ne hagyjon magára a melegítő kezelés alatt.
- Rossz vérkeringésű betegeket folyamatos megfigyelés alatt kell tartani hosszabb melegítő kezelés alatt.
- A melegítőtakaró nem perforált oldalát ne fordítsa a beteg felé. Mindig a perforált oldalát (az apró lyukakkal) tegye közvetlenül a betea bőrére.
- A műtőben kizárólag a Bair Hugger 500-as vagy 700-as sorozatú melegítőegységgel használja a melegítőtakarót, semmilyen más eszközzel ne.
- Ne használja a Bair Hugger 200-as sorozatú melegítőegységet a műtőben.
- Ne használja a Bair Hugger 800-as sorozatú szabályozható melegítőegységet semmilyen Bair Hugger melegítőtakaróval.
- Ne folytassa a melegítő kezelést, ha a piros, túlmelegedést jelző fény villog, és a figyelmeztető jelzés megszólal. Húzza ki a melegítőegységet a hálózatból, és hívjon szakképzett szerviztechnikust.
- Ne helyezzen rögzítőeszközöket (pl. biztonsági pántot vagy rögzítőtapaszt) a melegítőtakaró fölé.
- Ne helyezze a melegítőtakarót közvetlenül a diszperzív elektródapad fölé.

0:14 molende 1945 DTS DOC. 944 Flore File Policy File 1946 DA Data Page 247 gyógyszerbeadási módok esetén a melegítőegység gégecsövével ne

beteg sérülése vagy halála kockázatának csökkentése érdekében:

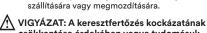
Ne használja a melegítőtakarót transzdermális

 Ne használja a melegítőtakarót transzdermál gyógyszeres tapaszon.



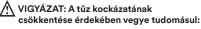
- Vigyázzon, hogy a melegítőtakaró vagy a fejkendő ne takarja el a beteg fejét vagy légutait, ha a beteget nem géppel lélegeztetik.
- FIGYELMEZTETÉS: A beteg leesése miatti lehetséges sérülés kockázatának csökkentése érdekében:

  Ne használja a melegítőtakarót a beteg



- csökkentése érdekében vegye tudomásul:

  Ez a melegítőtakaró nem steril, és
  KIZÁRÓLAG egyetlen betegen
- használható. Nem akadályozza meg a termék szennyeződését, ha lepedőt tesz a melegítőtakaró és a beteg közé.



- Ez a termék az 1. kategóriájú (normál) tűzveszélyességi osztályba tartozik a Fogyasztói termékbiztonsági bizottság gyúlékony szövetekre vonatkozó szabályozása szerint (16 CFR 1610). A szokásos biztonsági útmutatók szerint járjon el, ha nagy intenzitású hőforrást használ.
- / VIGYÁZAT: A hő okozta sérülés kockázatának csökkentése érdekében:: To reduce the risk of thermal injury:
  - Ne használja fel, ha a csomagolás fel van nyitva vagy sérült.
- VIGYÁZAT: A hő okozta sérülés, hipertermia vagy hipotermia kockázatának csökkentése érdekében:
  - A 3M a beteg maghőmérsékletének folyamatos figyelemmel követését ajánlja.
     A folyamatos figyelemmel követés hiányában azoknak a betegeknek a hőmérsékletét ellenőrizze 15 percenként, vagy az intézményi előírások szerint, akik nem képesek reagálni, kommunikálni és/vagy a
  - képesek reagálni, kommunikálni és/vagy a hőmérsékletet érzékelni.

    Ellenőrizze a bőrválaszt legalább 15 percenként, vagy az intézményi előírások szerint, azoknál a betegeknél, akik nem képesek reagálni, kommunikálni és/vagy a
  - A terápiás célt elérve, változtasson a levegő hőmérsékletén, vagy fejezze be a kezelést, ha emelkedett testhőmérsékletet mér, vagy ha a melegített területen nemkívánatos bőrválaszt észlel.

hőmérsékletet érzékelni.

#### Utasítások

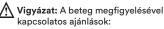
- A 3M™ Bair Hugger™ melegítőtakaró perforált oldalát (az apró lyukakkal ellátott oldalt) helyezze közvetlenül a beteg bőrére (A. ábra).
- Távolítsa el a ragasztószalag hátoldalát (ha van ilyen), és ragassza a melegifőtakarót a betegre (B. ábra). Ezzel megakadályozza, hogy a levegő a műtéti területre jusson.
   Opcionális: A hatékonyság növelése érdekében
- Opcionális: A hatékonyság növelése érdekébe takarja be a melegítőtakarót egy pokróccal vagy lepedővel.

  TIGYELMEZTETÉS: Ne helyezzen
  - rögzítőeszközöket (pl. biztonsági pántot vagy rögzítőtapaszt) a melegítőtakaró fölé.: Do not place patient securement device (i.e. safety strap or tape) over the warming blanket.
- FIGYELMEZTETÉS: Ne helyezze a melegítőtakarót közvetlenül a diszperzív elektródapad fölé. : Do not place the warming blanket directly over a dispersive electrode pad.
- A Bair Hugger melegítőegység gégecsövét csatlakoztassa a gégecső csatlakozójához (C. ábra). Csavaró mozdulattal csatlakoztassa, hogy szorosan rögzüljön. A gégecső végének középső részén egy jelölés látható, ami azt mutatja, hogy milyen mélyen kell behelyezni. Kézzel segítse a csatlakoztatást, hogy biztosan rögzüljön a gégecső.

melegitoegyseg gegecsovevel ne kezelje a betegeket. A gégecsövet mindig csatlakoztassa egy Bair Hugger melegítótakaróhoz, mielőtt megkezdené a melegítő kezelést.: Do not treat patients with the warming unit hose alone. Always attach the hose to a Bair Hugger warming blanket before providing warming therapy.

MEGJEGYZÉS: Lásd lent a Bair Hugger takaróval kapcsolatos speciális megjegyzéseket.

 A melegítő kezelés megkezdéséhez állítsa be a kívánt hőmérsékletet a melegítőegységen. (A melegítőegység adott modelljével kapcsolatban lásd a Kezelői kézikönyvet)



- A 3M a beteg maghőmérsékletének folyamatos figyelemmel követését ajánlja.
   A folyamatos figyelemmel követés hiányában azoknak a betegeknek a hőmérsékletét ellenőrizze 15 percenként, vagy az intézményi előírások szerint, akik nem
- képesek reagálni, kommunikálni és/vagy a hőmérsékletet érzékelni.

  Ellenőrizze a bőrválaszt legalább 15 percenként, vagy az intézményi előírások szerint, azoknál a betegeknél, akik nem képesek reagálni, kommunikálni és/vagy a hőmérsékletet érzékelni.
- A terápiás célt elérve, változtasson a levegő hőmérsékletén, vagy fejezze be a kezelést, ha emelkedett testhőmérsékletet mér, vagy ha a melegített területen nemkívánatos bőrválaszt észlel.
- A melegítő kezelés leállításához a használt melegítőegység modell szerint kapcsolja ki az egységet vagy kapcsolja készenléti állapotba. Húzza ki a melegítőegység gégecsövét a melegítőtakaróból, és a kórházi előírásoknak megfelelően ártalmatlanítsa a takarót.

### Speciális megfontolások: Két levegőbefúvó nyílású 54200-as modell

Két levegőbefúvó nyílású törzs takaró, 52200/52301-es modell Felsőtest takarók, és 57000-es sebészeti takaró Két levegőbefúvó nyílás, hogy az adott műtétnek megfelelően tudják használni. A gégecső csatlakozóját lezáró lapot helyezze a melegítő

megfelelően tudják használni. A gégecső csatlakozóját lezáró lapot helyezze a melegítő kezelés során nem használt gégecső csatlakozójába (D. ábra).

Fejkendő 54000/54200-as modell Törzs

takarók, 52200/52301 Felsőtest takarók és

57000 Sebészeti takaró

Ha a beteget intubálták és gépi úton lélegeztetik,
terítse a fejkendőt a beteg fejére és nyakára (E. ábra);
egyéb esetekben a kendőt hajtsa be a melegítőtakaró

terítse a fejkendőt a beteg fejére és nyakára (E. ábra); egyéb esetekben a kendőt hajtsa be a melegítőtakaró csatornái közé, a beteg fejétől távol.

FIGYELMEZTETÉS: : Vigyázzon, hogy a melegítőtakaró vagy a fejkendő ne takarja el a beteg fejét vagy légutait, ha a beteget nem géppel lélegeztetik.
Felsőtest takaró, 52200/52301-es

# modell (opcionális)

Húzza ki a melegítőtakaró felső és alsó szélénél található rögzítőszalagfüleket. Kösse le a rögzítőszalagokat, hogy a felfújt takaró ne emelkedjen fel a betegről. Ha a felsőtestre való takarót csak az egyik karon kívánja használni, akkor a melegítőtakaró egyik felét lekötözheti úgy, hogy ragtapaszt teker köré, vagy behajtja a beteg alá (F. ábra).

#### 61000-as modellek Teljes test sebészeti és 31500-as Többszörös hozzáférésű posztoperatív takarók

A műtéti terület elérését biztosító panel használatához erősen hűzza meg a fület a melegítőtakaró szélénél. A takaró közepén távolítsa el a ragasztószalag hátoldalát. A panelt hajtsa hátra és nyomja a betegre a ragasztószalagot. Hűzza le a panelt a ragasztóról, hogy elengedje (G. ábra).

## 30500-as modell Mellkasi hozzáférésű takaró

Emelje fel az átlátszó műanyag lapot, hogy kezelni tudja a beteg felsőtestét (H. ábra).

A 3M, a Bair Hugger és a Bair Hugger logó a 3M védjegyei.

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Termoregulační systém 3M™ Bair Hugger™ je určen k prevenci a ošetření hypotermie. Mimoto lze termoregulační systém použít k zajištění tepelného komfortu pacienta v podmínkách, kdy může být pacientovi příliš horko, nebo příliš zima. Termoregulační systém lze použít u dospělých i dětských pacientů.

- NESTERII NÍ.
- Federální zákon (USA) omezuje prodej tohoto prostředku na licencované odborné zdravotnické pracovníky nebo na základě jejich objednávky.

### Kontraindikace, varování a výstrahy

#### Vysvětlení významu jednotlivých klasifikací nebezpečí



VAROVÁNÍ:
Označuje nebezpečné situace, kterých je nutno se vyvarovat, jinak hrozí nebezpečí smrti nebo vážného poranění.



**VÝSTRAHA:**Označuje nebezpečné situace, kterých je nutno se vyvarovat, jinak hrozí nebezpečí lehkého nebo středně těžkého poranění.



### KONTRAINDIKACE: Aby se snížilo riziko tepelného poranění:

V době, kdy je zasvorkovaná aorta, nepřivádějte teplo na dolní končetiny. Při aplikaci tepla na ischemické končetiny může dojít k tepelnému poranění.



#### VAROVÁNÍ: Aby se snížilo riziko tepelného poranění:

- Nepoužívejte k zahřívání pacientů samotnou hadici ohřívací jednotky Bair Hugger. Hadici vždy připojte k zahřívacímu blanketu Bair Hugger ještě před zahájením zahřívání.
- Pacient nesmí ležet na hadici ohřívací jednotky.
- Během zahřívání nesmí být hadice ohřívací jednotky v přímém kontaktu s pacientovou kůží.
- Během zahřívání nenechávejte novorozence, batolata, děti a další ohrožené skupiny pacientů bez dozoru.
- Pacienty se špatnou perfuzí nenechávejte během déletrvajícího zahřívání bez monitoringu.
- Neumísťuite neperforovanou stranu zahřívacího blanketu k tělu pacienta. Perforovanou stranu (s malými otvory) vždy přiložte přímo na pacienta, takže je v kontaktu s pacientovou kůží.
- Na operačním sále nepoužívejte tento zahřívací blanket s žádným jiným přístrojem než s ohřívací jednotkou Bair Hugger 500 nebo sérií 700.
- Nepoužívejte ohřívací jednotku série Bair Hugger 200 na operačním sále.
- S žádnou zahřívacím blanketem Bair Hugger nepoužívejte pacientem nastavitelnou ohřívací jednotku série Bair Hugger 800
- Nepokračujte v zahřívání, jestliže se rozsvítí kontrolka Over-Temp (Překročení teploty) a zazní akustický alarm. Odpojte ohřívací jednotku ze zásuvky a obraťte se na kvalifikovaného servisního technika.
- Neumísťujte prostředek pro fixaci pacienta (tj. bezpečnostní popruh nebo pás) přes zahřívací blanket.
- Neumísťujte zahřívací blanket přímo přes podložku disperzní elektrody.



#### 🔨 VAROVÁNÍ: Aby se snížilo riziko poranění nebo smrti pacienta v důsledku změněného vstřebávání léku:

• Nepoužívejte zahřívací balnket přes náplasti pro transdermální aplikaci léků.



#### VAROVÁNÍ. Aby se snížilo riziko poranění v důsledku interference s ventilací:

Zahřívací blanket nebo rouška pro hlavu nesmí zakrývat pacientovu hlavu nebo dýchací cesty, když pacient není mechanicky ventilován.

#### NAROVÁNÍ: Aby se snížila možnost poranění v důsledku pádu pacienta:

 Nepoužívejte zahřívací blanket k přenášení nebo posouvání pacienta.

### VÝSTRAHA: Pro snížení rizika křížové kontaminace:

Tato zahřívací přikrývka není sterilní a je určena k použití POUZE u jednoho pacienta. Prostěradlo vložené mezi zahřívací blanket a pacienta nezabrání kontaminaci výrobku.

## NÝSTRAHA: Pro snížení rizika požáru:

 Tento výrobek je klasifikován jako výrobek třídy I Normální hořlavost, jak je definováno v předpisu o hořlavých textiliích Komise pro bezpečnost spotřebních výrobků, 16 CFR 1610. Při použití tepelných zdrojů s vysokou intenzitou dodávaného tepla dodržujte standardní bezpečnostní protokoly.



### ∕∱ VÝSTRAHA: Aby se snížilo riziko tepelného poranění:

 Nepoužívejte, pokud byl primární obal otevřen či poškozen.

### VÝSTRAHA: Aby se snížilo riziko tepelného poranění, hypertermie nebo hypotermie:

- Společnost 3M doporučuje kontinuálně monitorovat teplotu jádra. Při neexistenci kontinuálního monitorování monitoruite minimálně každých 15 minut nebo podle interních směrníc teplotu pacientů, kteří nejsou schopni reagovat, komunikovat a/nebo kteří nejsou schopni cítit teplotu.
- Minimálně každých 15 minut nebo podle interních směrnic sledujte reakce kůže pacientů, kteří nejsou schopni reagovat, komunikovat a/nebo kteří nejsou schopni cítit teplotu.
- Když je dosaženo cíle terapie, jestliže jsou zaznamenány zvýšené teploty nebo jestliže v zahřívané oblasti existuje negativní reakce kůže, upravte teplotu vzduchu nebo terapii přerušte.

- Přiložte perforovanou stranu zahřívacího blanketu 3M™ Bair Hugger™ (strana s malými otvory) přímo na pacienta, takže je v kontaktu s pacientovou kůží (obrázek A).
- Kde je to vhodné, odstraňte ochrannou vrstvu z proužku lepicí pásky a přilepte zahřívací blanket k pacientovi (obrázek B). Tak se zabrání proudění vzduchu k místu zákroku.

Volitelně: Aby se zvýšila účinnost, položte na blanket příkrývku jednu textilní přikrývku nebo prostěradlo.



Narování: Neumísťujte prostředek pro fixaci pacienta (tj. bezpečnostní popruh nebo pás) přes zahřívací blanket.



🕂 Varování: Neumísťujte zahřívací blanket přímo přes podložků disperzní elektrody.

Zasuňte konec hadice ohřívací jednotky Bair Hugger do portu hadice (obrázek C). Otáčením hadicí zajistěte její správné upevnění. U středního řezu na konci hadice je značka indikující optimální hloubku zasazení hadice. Podepřete hadici, aby se zajistilo bezpečné připojení.

Narování: Nepoužívejte k zahřívání pacientů samotnou hadici ohřívací jednotky. Hadici vždy připojte k zahřívacímu blanketu Bair Hugger ještě před zahájením zahřívání.

#### POZNÁMKA: Viz níže uvedená zvláštní upozornění týkající se blanketů Bair Hugger.

Na ohřívací jednotce zvolte požadované nastavení teploty pro zahájení zahřívání. (Viz návod k obsluze pro váš konkrétní model ohřívací jednotky.)



#### 🔨 **Výstraha:** Doporučení pro monitorování pacienta:

 Společnost 3M doporučuje kontinuálně monitorovat teplotu jádra. Při neexistenci kontinuálního monitorování monitorujte minimálně každých 15 minut nebo podle interních směrnic teplotu pacientů, kteří nejsou schopni reagovat, komunikovat a/nebo kteří nejsou schopni cítit teplotu.

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interních směrnic sledujte reakce kůže pacientů, kteří nejsou schopni reagovat, komunikovat a/nebo kteří nejsou schopni cítit teplotu.

- Když je dosaženo cíle terapie, jestliže jsou zaznamenány zvýšené teploty nebo jestliže v zahřívané oblasti existuje negativní reakce kůže, upravte teplotu vzduchu nebo terapii přerušte.
- Podle toho, jaký používáte model ohřívací jednotky, přerušíte zahřívání vypnutím jednotky nebo přepnutím do pohotovostního režimu. Odpojte hadici ohřívací jednotky od zahřívacího blanketu a blanket zlikvidujte podle interních směrnic nemocnice.

#### Zvláštní upozornění:

Dvojí port pro model 54200 blanketu na trup s dvojím hadicovým portem, přikrývky 52200/52301 na horní část těla a přikrývka 57000 pro chirurgický přístup

Jsou připraveny dva porty hadice pro použití podle výběru lékaře. Do portu hadice, který se během zahřívání nepoužívá, umístěte vyjímatelnou kartu pro port hadice (obrázek D).

Rouška pro hlavu pro modely přikrývky 54000/54200 na trup, přikrývky 52200/52301 na horní část těla a přikrývky 57000 pro chirurgický přístup

Jestliže je pacient intubován a ventilován, položte roušku pro hlavu přes pacientovu hlavu a krk (obrázek E): iinak zastrčte roušku mezi kanály zahřívací přikrývky, mimo oblast pacientovy hlavy.

# mechanicky ventilován.

pro hlavu nesmí zakrývat pacientovu hlavu nebo dýchací cesty, když pacient není

#### Přikrývky 52200/52301 na horní část těla (volitelná možnost)

Zatáhněte za úchyty oddělitelných vázacích pásek umístěné ve středu horního a dolního okraje zahřívacího blanketu. Uvažte tyto pásky, aby se zabránilo zvedání nafouknutého blanketu od těla pacienta. Pro použití blanketu na horní část těla s jednou opěrkou paže je možné jednu polovinu zahřívací přikrývky podvázat tak, že se kolem ní ovine páska, nebo se zastrčí pod pacienta (obrázek F).

#### Celotělové chirurgické přikrývky 61000 a pooperační přikrývky 31500 s různými přístupy

Pro použití přístupových panelů trhněte za neodstřižený úchyt na okraji zahřívací přikrývky. Odstraňte ochrannou vrstvu z proužku lepicí pásky na středu přikrývky. Přehněte přístupový panel směrem od sebe a přitlačte ho na odkrytou lepicí pásku. Když budete chtít panel uvolnit, odtáhněte ho od lepicí pásky (Obrázek G).

#### Přikrývka 30500 s přístupem ke hrudi

Pro ošetření pacienta v horní části těla zvedněte průhlednou plastovou roušku (obrázek H).

3M, Bair Hugger a logo Bair Hugger jsou ochranné známky společnosti 3M.

V Kanadě používáno na základě licence. © 2016, 3M. Všechna práva vyhrazena.

## NAUDOJIMO INSTRUKCIJOS

#### Naudojimo indikacijos

"3M™ Bair Hugger™" temperatūros valdymo sistema yra skirta apsaugoti ir gydyti nuo hipotermijos. Be to, temperatūros valdymo sistema gali būti naudojama siekiant užtikrinti malonią šilumą, kai dėl tam tikrų sąlygų pacientams gali būti per šilta arba per šalta. Temperatūros valdymo sistemą galima naudoti suaugusiesiems ir vaikams.

- NESTERILL
- Remiantis federaliniu įstatymu (JAV) leidimas parduoti šį įtaisą yra suteikiamas tik licenciją turinčiam sveikatos priežiūros specialistui ar jo nurodymu.

#### Kontraindikacijos, įspėjimai ir perspėjimai

#### Signalinių žodžių pasekmių paaiškinimas



#### **ĮSPĖJIMAS**

Reiškia pavojingą situaciją, kuri, jeigu jos nebus išvengta, gali lemti mirtį arba sunkų sužalojimą.



#### **PERSPĖJIMAS**

Reiškia pavojingą situaciją, kuri, jeigu jos nebus išvengta, gali lemti nedidelį arba vidutinį sužalojimą.



#### ★ KONTRAINDIKACIJOS Kad sumažintumėte šiluminio sužalojimo riziką:

 nešildykite apatinių galūnių aortos užspaudimo metu. Šildant išemijos veikiamos galūnės gali būti nudegintos.



#### 🔨 ĮSPĖJIMAS Kad sumažintumėte šiluminio sužalojimo riziką:

- nešildykite pacientų vien tik "Bair Hugger" šildomojo įtaiso žarnele. Prieš pradėdami šildymo procedūrą, visuomet prijunkite žarnelę prie "Bair Hugger" šildomosios antklodės.
- Neleiskite pacientui gulėti ant šildomojo itaiso žarnelės.
- Neleiskite šildomojo įtaiso žarnelei tiesiogiai liestis prie paciento odos, kai pacientas šildomas
- Nepalikite naujagimių, kūdikių, vaikų ir kitų pažeidžiamų pacientų neprižiūrimų, kai iie šildomi.
- Pacientų su prasta kraujotaka negalima palikti nestebimų atliekant ilgalaikį šildymą.
- Neklokite šildomosios antklodės ant paciento neperforuotąja puse. Antklodę visuomet klokite perforuotąja puse (kurioje yra mažos

skylutės) tiesiai ant paciento, kad ji liestųsi su paciento oda.

- Operacinėje nenaudokite šios šildomosios antklodės su jokiu kitu prietaisu, išskyrus "Bair Hugger" 500 ar 700 serijos šildomąjį įtaisą.
- Nenaudokite "Bair Hugger" 200 serijos šildomojo įtaiso operacinėje.
- Nenaudokite "Bair Hugger" 800 serijos paciento reguliuojamo šildomojo įtaiso su bet kokia "Bair Hugger" šildomąja antklode.
- Jei šviečia raudona per aukštos temperatūros indikatoriaus lemputė ir skamba įspėjamasis signalas, šildymo procedūrą reikia nutraukti. Atjunkite šildomąjį įtaisą nuo maitinimo lizdo ir susisiekitė su kvalifikuotu priežiūros techniku.
- Nedėkite paciento tvirtinimo prietaiso (t. y. saugos diržo ar juostos) ant šildomosios antklodės.
- Nedėkite šildomosios antklodės tiesiai ant pasyvaus elektrodo pagalvėlės.

#### N ĮSPĖJIMAS Siekdami sumažinti paciento sužalojimo arba mirties riziką dėl pasikeitusio vaistų patekimo į organizmą:

• nenaudokite šildomosios antklodės ant transderminių vaistų pleistrų.

### 🄼 ĮSPĖJIMAS. Norėdami sumažinti sužalojimo riziką dėl trukdžių ventiliavimui:

neleiskite šildomajai antklodei arba galvos uždangalui uždengti paciento galvą arba kvėpavimo takus, kai pacientas nėra ventiliuojamas mechaniškai.

#### / ĮSPĖJIMAS Norėdami sumažinti galimo sužalojimo dėl paciento kritimo riziką:

• nenaudokite šildomosios antklodės paciento perkėlimui.



#### PERSPĖJIMAS Norėdami sumažinti kryžminės taršos riziką:

 ši šildomoji antklodė nesterili ir skirta naudoti TIK vienam pacientui. Įdėjus paklodę tarp šildomosios antklodės ir paciento, nuo gaminio užteršimo nebus apsaugota.



### PERSPĖJIMAS Kad sumažintumėte gaisro riziką:

• šis gaminys priskiriamas normalaus degumo klasei I, kaip apibrėžta Vartotojų gaminių saugos komisijos degių medžiagų reglamente 16 CFR 1610. Kai naudojate didelio intensyvumo šilumos šaltinius, laikykitės standartinių saugos protokolų.

#### 0:15 materiana final Nazintinste Doc. 912-1 tem Filad blaka 3/min Zeių Pragga 250 šiluminio sužalojimo riziką: įstaigos protokolą.

nenaudokite, jeigu pirminė pakuotė anksčiau buvo atidaryta arba pažeista.



#### PERSPĖJIMAS Kad sumažintumėte šiluminio sužalojimo, hipertermijos ar hipotermijos rizika:

- "3M" rekomenduoja nuolat stebėti vidinę temperatūrą. Jeigu nuolatinio stebėjimo nėra, stebėkite pacientų, kurie negali reaguoti, komunikuoti ir (arba) jausti temperatūros, temperatūrą bent kas 15 minučių arba pagal įstaigos protokolą.
- Stebėkite pacientų, kurie negali reaguoti, komunikuoti ir (arba) jausti temperatūros, odos reakcijas bent kas 15 minučių arba pagal istaigos protokola.
- Sureguliuokite oro temperatūrą arba nutraukite procedūrą, kai pasiekiamas terapinis tikslas, jeigu registruojama padidėjusi temperatūra arba jeigu šildomoje srityje kilo nepageidaujama odos reakcija.

#### Instrukcijos

- Uždėkite "3M™ Bair Hugger™" šildomosios antklodės perforuotą pusę (su mažomis skylutėmis) tiesiai ant paciento taip, kad ji liestusi su paciento oda (A pav.).
- Jeigu taikytina, nuimkite lipnios juostelės pagrindą ir prilipdykite šildomąją antklodę prie paciento (B pav.). Taip oras negalės patekti į operuojamą vietą.

Pasirinktinai: uždėkite vieną medžiaginę antklodę arba paklodę ant šildomosios antklodės, kad padidintumėte veiksmingumą.



🔨 Įspėjimas: Nedėkite paciento tvirtinimo prietaiso (t. y. saugos diržo ar juostos) ant šildomosios antklodės.



Įspėjimas: Nedėkite šildomosios antklodės tiesiai ant pasyvaus elektrodo pagalvėlės.

Įkiškite "Bair Hugger" šildomojo įtaiso žarnelės galą į žarnelės jungtį (C pav.). Sukamuoju judesiu užtikrinkite tvirtą sujungimą. Vizuali žyma yra maždaug žarnelės galo vidurinėje dalyje, kad žinotumėte, kiek giliai įkišote žarnelę. Prilaikykite žarnelę, kad užtikrintumėte saugų jos pritvirtinimą.



İşpêjimas: Nešildykite pacientų vien tik šildomojo įtaiso žarnele. Prieš pradėdami šildymo procedūrą, visuomet prijunkite žarnelę prie "Bair Hugger šildomosios antklodės.

#### PASTABA. Skaitykite specialius patarimus dėl "Bair Hugger" antklodžių, parodytų toliau.

Šildomajame įtaise pasirinkite norimą temperatūros nuostatą ir pradėkite šildymo procedūrą. (Konkretų šildomojo įtaiso modelį rasite naudotojo vadove)



<u>↑</u> **Dėmesio!** Pacientų stebėjimo rekomendacijos:

> "3M" rekomenduoja nuolat stebėti vidinę temperatūrą. Jeigu nuolatinio stebėjimo nėra, stebėkite pacientų, kurie negali reaguoti, komunikuoti ir (arba) jausti temperatūros,

- Stebėkite pacientų, kurie negali reaguoti, komunikuoti ir (arba) jausti temperatūros, odos reakcijas bent kas 15 minučių arba pagal įstaigos protokolą.
- Sureguliuokite oro temperatūrą arba nutraukite procedūrą, kai pasiekiamas terapinis tikslas, jeigu registruojama padidėjusi temperatūra arba jeigu šildomoje srityje kilo nepageidaujama odos reakcija.
- Atsižvelgdami į naudojamą šildomojo įtaiso modelį, išjunkite įtaisą arba perjunkite jį į parengties režimą, kad nutrauktumėte šildymo procedūrą. Atjunkite šildomojo įtaiso žarnelę nuo šildomosios antklodės ir išmeskite antklodę pagal ligoninės nuostatus.

#### Specialūs aspektai:

Dviguba jungtis 54200 modelio dvigubos jungties liemens antklodei, 52200 / 52301 viršutinės kūno dalies antklodėms ir 57000 chirurginės prieigos antklodei

Parūpintos dvi jungtys žarnelei gydytojui pasirinkti. Įdėkite išimamą žarnelės jungties kortelę į žarnelės jungtį, kuri nenaudojama šildymo procedūros metu (D pav.).

Galvos uždangalas 54000 / 54200 modelių liemens antklodėms, 52200 / 52301 viršutinės kūno dalies antklodėms ir 57000 chirurginės prieigos antklodei

Jeigu pacientas yra intubuotas ir ventiliuojamas, uždėkite galvos uždangalą ant paciento galvos ir kaklo (E pav.); kitu atveju, įkiškite uždangalą tarp šildomosios antklodės kanalų, toliau nuo paciento galvos.



🖍 Įspėjimas: neleiskite šildomajai antklodei arba galvos uždangalui uždengti paciento galvą arba kvėpavimo takus, kai pacientas nėra ventiliuojamas mechaniškai

#### 52200 / 52301 modelių viršutinės kūno dalies antklodės (įsigyjamos pasirinktinai)

Patraukite raištelių kilpeles, esančias šildomosios antklodės viršutinio ir apatinio krašto viduryje. Suriškite šias juosteles, kad pripūsta antklodė nepasikeltų nuo paciento. Norint naudoti viršutinės kūno dalies antklode su vienu alkūnramsčiu, vieną šildomosios antklodės pusę galima pritvirtinti užvyniojus juostą aplink ją arba pakišus ją po pacientu (F pav.).

#### 61000 modelio viso kūno chirurginė ir 31500 kelių prieigų pooperacinė antklodės

Norėdami naudoti prieigos langelius, nuplėškite nenukirptą kilpelę šildomosios antklodės krašte. Nuimkite antklodės viduryje esančios lipnios juostelės pagrindą. Atlenkite prieigos langelį atgal ir paspauskite prie atviros lipnios juostelės. Atitraukite langelį nuo juostelės, kad atlaisvintumėte (G pav.).

## 30500 modelio krūtinės prieigos antklodė

Pakelkite permatomą plastikinį uždangalą, kad galėtumėte pasirūpinti paciento viršutine kūno dalimi (H pav.).

"3M", "Bair Hugger" ir "Bair Hugger" logotipas yra "3M" prekių ženklai.

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## 📵 ИНСТРУКЦИИ ПО ПРИМЕНЕНИЮ

#### Показания к применению

Система управления температурой 3M™ Bair Hugger™ предназначена для профилактики и лечения гипотермии. Кроме того, систему управления температурой можно использовать для поддержания комфортной для пациента температуры в условиях, которые могут привести к перегреву или переохлаждению пациента. Система управления температурой может использоваться как для взрослых, так и для детей.

- НЕСТЕРИЛЬНО.
- Согласно федеральному закону США продажа этого устройства разрешена только лицензированным работникам здравоохранения или по их заказу.

#### Противопоказания, предупреждения и предостережения

### Пояснение опасностей, на которые **УКАЗЫВАЮТ СИГНАЛЬНЫЕ СЛОВА**



#### предупреждение.

Указывает на опасную ситуацию, которая может привести к смерти или тяжелой травме.



## предостережение.

Указывает на опасную ситуацию, которая, если ее не избежать, может привести к травме легкой или . средней тяжести.

приведенные далее указания.

Не проводите процедуру обогрева нижних конечностей пациента во время пережатия аорты. Термическая травма может возникнуть при тепловом воздействии на ишемизированные конечности.

#### ПРЕДУПРЕЖДЕНИЕ. Чтобы снизить риск термической травмы, соблюдайте приведенные далее указания

- Не производите обогрев пациентов только с помощью шланга устройства для обогрева Bair Hugger. Всегда подсоединяйте шланг к обогревающему одеялу Bair Hugger, прежде чем начинать процедуру обогрева.
- Следите за тем, чтобы пациент не ложился на шланг устройства для обогрева.
- Следите за тем, чтобы шланг устройства для обогрева не соприкасался с кожей пациента во время процедуры обогрева.
- Во время процедуры обогрева не оставляйте без присмотра новорожденных, младенцев, детей и других пациентов, требующих особого внимания.
- Во время продолжительной процедуры обогрева не оставляйте без присмотра пациентов с недостаточной перфузией.
- Не укрывайте пациента неперфорированной стороной обогревающего одеяла. Всегда размещайте перфорированную сторону (с небольшими отверстиями) непосредственно на пациенте, обеспечивая контакт с кожей.
- В операционной не используйте это обогревающее оделяло вместе с каким-либо устройством, кроме устройства для обогрева Bair Hugger серии 500 или 700.
- Не используйте в операционной устройство для обогрева Bair Hugger серии 200.
- Не используйте регулируемое устройство для обогрева Bair Hugger серии 800 в комплексе с обогревающим одеялом Bair Hugger любой модели.
- Прекратите процедуру обогрева, если загорится красный световой индикатор превышения температуры и включится сигнал тревоги. Отключите устройство для обогрева от источника питания и свяжитесь с квалифицированным специалистом по техническому обслуживанию.
- Не размещайте устройство фиксации пациента (например, предохранительный ремень или ленту) на обогревающем одеяле.
- Не размещайте обогревающее одеяло непосредственно на прокладке пассивного электрода.

、ПРЕДУПРЕЖДЕНИЕ. Чтобы снизить риск травмирования или смерти пациента из-за изменения метода введения препаратов, соблюдайте приведенные далее указания.

Не размещайте обогревающее одеяло поверх трансдермального пластыря

🤨 ПРЕДУПРЕЖДЕНИЕ. Для того чтобы снизить риск получения травмы пациентом . из-за нехватки воздуха, соблюдайте приведенные далее указания.

Следите за тем, чтобы обогревающее одеяло или покрывало для головы не закрывало голову пациента и не блокировало дыхательные пути в том случае, если не применяется искусственная вентиляция легких.

**∖** ПРЕДУПРЕЖДЕНИЕ. Для того чтобы снизить вероятность травмирования пациента вследствие падения, соблюдайте приведенные далее указания.

• Не используйте обогревающее одеяло для переноса или перемещения пациента.

ПРЕДОСТЕРЕЖЕНИЕ. Чтобы снизить риск перекрестного загрязнения, соблюдайте приведенные далее указания.

Это обогревающее одеяло нестерильно и предназначено ТОЛЬКО для одного пациента. Использование простыни между обогревающим одеялом и пациентом не предотвратит загрязнение продукта.

# далее указания.

В соответствии со стандартом 16 CFR (часть 1610) Комиссии по безопасности потребительских товаров в отношении легковоспламеняющихся материалов данное устройство классифицируется .. как продукт класса I (нормальная воспламеняемость). При использовании источников тепла высокой интенсивности всегда руководствуйтесь протоколами стандартов безопасности.

ПРЕДОСТЕРЕЖЕНИЕ. Чтобы снизить риск термической травмы, соблюдайте . приведенные далее указания.

• Не используйте, если первичная упаковка вскрыта или повреждена.

↑ ПРЕДОСТЕРЕЖЕНИЕ. Чтобы снизить риск . . термической травмы, гипертермии или гипотермии, соблюдайте приведенные далее указания.

- Компания 3М рекомендует осуществлять постоянный мониторинг внутренней температуры пациента. При отсутствии постоянного мониторинга контролируйте температуру пациентов, не имеющих возможность реагировать надлежащим образом, общаться и (или) не чувствующих температуру, по крайней мере каждые 15 минут или в соответствии с принятыми в учреждении правилами.
- Проверяйте состояние кожи пациентов, которые не могут ощущать температуру или же не способны реагировать и сообщать о своих ощущениях, как минимум каждые 15 минут или в соответствии с местным протоколом
- Отрегулируйте температуру воздуха или прервите процедуру, если достигнута цель лечения, отмечается рост температуры или в зоне нагрева обнаружена нежелательная кожная реакция.

### Инструкции

- Разместите перфорированную сторону обогревающего одеяла 3М™ Bair Hugger™ (сторону с небольшими отверстиями) непосредственно на пациенте так, чтобы она касалась его кожи (рисунок А).
- Если применимо, снимите бумажную подложку 2. с полоски клейкой ленты и прикрепите обогревающее одеяло к пациенту (рисунок В). Это предотвратит движение воздуха в сторону операционного поля.

Дополнительно. Для повышения эффективности разместите одно тканевое одеяло на обогревающем одеяле.



Предупреждение. Не размещайте устройство фиксации пациента (например, предохранительный ремень или ленту) на обогревающем одеяле.



Предупреждение. Не размещайте обогревающее одеяло непосредственно на прокладке пассивного электрода.

3. Вставьте конец шланга устройства для обогрева Bair Hugger в разъем для шланга (рисунок С). Вкручивайте до плотной посадки. Визуальная метка, указывающая глубину введения шланга, расположена в средней части наконечника шланга. Придерживайте шланг для обеспечения надежности крепления.



**Предупреждение.** Не производите обогрев пациентов только с помощью шланга устройства для обогрева Bair Hugger. Всегда подсоединяйте шланг к обогревающему одеялу Bair Hugger, прежде чем начинать процедуру обогрева.

#### ПРИМЕЧАНИЕ. См. особые указания для использования согревающих одеял Bair Hugger, приведенные ниже.

Выберите необходимую температуру на устройстве для обогрева, чтобы начать процедуру обогрева. (См. руководство по эксплуатации вашей модели устройства для обогрева.)



**Предостережение.** Рекомендации по мониторингу состояния пациента.

Компания 3М рекомендует осуществлять постоянный мониторинг внутренней температуры пациента. При отсутствии

# 0:15-md-02666-1NE-DTS олирунес. 912-1 для головина имеющих рисунок Е). В противном случае заправьте ее

возможность реагировать надлежащим образом, общаться и (или) не чувствующих температуру, по крайней мере каждые 15 минут или в соответствии с принятыми в учреждении правилами.

- Проверяйте состояние кожи пациентов, которые не могут ощущать температуру или же не способны реагировать и сообщать о своих ощущениях, как минимум каждые 15 минут или в соответствии с местным протоколом.
- Отрегулируйте температуру воздуха или прервите процедуру, если достигнута цель лечения, отмечается рост температуры или в зоне нагрева обнаружена нежелательная кожная реакция.
- 5 Чтобы прекратить процедуру обогрева, выключите устройство или переведите его в режим ожидания (в зависимости от используемой модели устройства для обогрева). Отсоедините шланг устройства для обогрева от обогревающего одеяла и утилизируйте одеяло согласно правилам медицинского учреждения.

#### Особые указания.

Два разъема у моделей одеяла для туловища 54200, одеял для верхней части тела 52200/52301 и одеяла с хирургическим доступом 57000

Для удобства врача имеются два разъема для шланга. Разместите съемную пластину разъема для шланга на разъеме для шланга, неиспользуемом во время обогрева (рисунок D).

Пленка для головы у моделей одеял для туловища 54000/54200, одеял для верхней части тела 52200/52301 и одеял с хирургическим доступом 57000

Если пациент интубирован и подключен к системе искусственной вентиляции легких, разместите

между каналами обогревающего одеяла, убрав с головы пациента.



Предупреждение. Следите за тем, чтобы обогревающее одеяло или покрывало для головы не закрывало голову пациента и не блокировало дыхательные пути в том случае, если не применяется искусственная вентиляция легких.

#### Одеяла для верхней части тела моделей 52200/52301 (дополнительно)

Потяните за полосы на стяжках, расположенные по центру верхнего и нижнего краев обогревающего одеяла. Затяните эти стяжки, чтобы одеяло, наполненное воздухом, не спадало с пациента (рисунок В). Чтобы использовать одеяло для верхней части тела с одним подлокотником, можно прикрепить одну половину обогревающего одеяла, обмотав вокруг подлокотника ленту или заправив одеяло под пациента (рисунок F).

Хирургическое одеяло для всего тела модели 61000 и одеяло для пациентов после операции с возможностью доступа к нескольким частям тела модели 31500

Чтобы воспользоваться секциями доступа, оторвите несрезаемую отгибаемую часть с края обогревающего одеяла. Снимите подкладку с полоски клейкой ленты, расположенной в центре одеяла. Отверните секцию доступа и надавите на клейкую ленту, с которой сняли подкладку. Чтобы закрыть секцию, оторвите ее от клейкой ленты (рисунок G).

#### Одеяло модели 30500 с доступом к груди

Разверните прозрачную пластиковую пленку, чтобы обеспечить уход за пациентом в верхней части тела (рисунок H).

3M, Bair Hugger и логотип Bair Hugger являются товарными знаками компании 3М.

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# <sup>®</sup> KULLANIM TALİMATLARI

## Kullanım Endikasyonları

3M™ Bair Hugger™ Sıcaklık Yönetim Sistemi hipotermiyi önlemek ve tedavi etmek için tasarlanmıştır. Ayrıca sıcaklık yönetim sistemi, hastaların çok sıcak veya çok soğuk hissetmesine neden olabilecek koşulların varlığında hastaya termal konfor sağlamak için de kullanılabilir. Sıcaklık yönetim sistemi yetişkin ve pediyatrik hastalarda kullanılabilir.

- STERİL DEĞİLDİR.
- Federal yasa (ABD), bu cihazın sadece lisanslı bir sağlık uzmanı tarafından satın alınmasına veya böyle bir uzmanın siparişiyle satılmasına izin vermektedir.

#### Kontrendikasyonlar, Uyarılar ve İkazlar

#### Uyarı İfadelerinin Açıklaması



Önlem alınmadığı takdirde ölüm veya ciddi yaralanmalarla sonuçlanabilecek tehlikeli bir durumu belirtir.



#### DİKKAT:

Önlem alınmadığı takdirde küçük veya orta dereceli yaralanmalarla sonuçlanabilecek tehlikeli bir durumu belirtir.



#### ★ KONTRENDİKASYON: Termal yaralanma riskini azaltmak için:

 Aortik kros klempleme sırasında alt ekstremitelere ısı uygulamayın. İskemik ekstremitelere ısı uygulamak termal yaralanmaya neden olabilir.

#### **Ù UYARI: Termal yaralanma riskini** azaltmak için:

- Hastaları yalnızca Bair Hugger ısıtma ünitesinin hortumuyla tedavi etmeyin. Isıtma tedavisi sağlamadan önce hortumu her zaman Bair Hugger ısıtma battaniyesine bağlayın.
- Hastanın ısıtma ünitesi hortumunun üzerine yatmasını engelleyin.
- Isitma tedavisi sırasında ısıtma ünitesi hortumunun hastanın cildine doğrudan temas etmesini engelleyin.

- Isitma tedavisi sırasında yenidoğan, bebek, çocuk ve diğer zayıf hastaları gözetimsiz bırakmayın.
- Uzun ısıtma tedavisi sırasında perfüzyonu zayıf olan hastaları izlemeyi bırakmayın.
- Isıtma battaniyesinin gözeneksiz tarafını hastanın üzerine örtmeyin. Her zaman, gözenekli tarafı (küçük delikli) hastanın cildine doğrudan temas edecek şekilde hastanın üzerine örtün.
- Ameliyathanede, ısıtma battaniyesini Bair Hugger 500 ya da 700 serisi ısıtma ünitesi dısında bir cihazla birlikte kullanmavın.
- Ameliyathanede, Bair Hugger 200 serisi ısıtma ünitesi kullanmayın.
- Bair Hugger 800 serisi hasta tarafından ayarlanabilir ısıtma ünitesini bir Bair Hugger ısıtma battaniyesiyle birlikte kullanmayın.
- Kırmızı Over Temp (Aşırı Sıcaklık) gösterge ışığı yanıyorsa ve alarm çalıyorsa ısıtma tedavisine devam etmeyin. İsıtma ünitesinin fişini çekin ve yetkili bir servis teknisyeni ile görüşün.
- Isıtma battaniyesinin üzerine hasta sabitleme cihazı (emniyet kemeri veya bandı gibi) yerleştirmeyin.
- Isıtma battaniyesini doğrudan dispersif elektrot pedi üzerine yerleştirmeyin.

#### M UYARI: Düzenlemeli ilaç uygulaması nedeniyle hastanın yaralanma veya ölüm riskini azaltmak için:

• Isıtma battaniyesini transdermal ilaç bantları üzerinde kullanmayın.



#### nedeniyle yaralanma riskini azaltmak için:

 Hastanın ventilasyonu mekanik olarak sağlanmıyorsa, ısıtma battaniyesinin veya kafa örtüsünün hastanın başını veya hava yolunu örtmesini engelleyin.



#### 🥂 UYARI: Hastanın düşmesi nedeniyle yaralanma potansiyelini azaltmak için:

 Hastayı taşımak veya yerini değiştirmek için ısıtma battaniyesini kullanmayın.

## Kılavuzuna bakın)

Bu ısıtma battaniyesi steril değildir ve YALNIZCA tek bir hastada kullanım için tasarlanmıştır. Hasta ile ısıtma battanivesi arasına çarşaf yerleştirilmesi ürünün kontamine olmasını önlemez.

### N DİKKAT: Yangın riskini azaltmak için:

 Bu ürün, Tüketici Ürünleri Güvenliği Komisyonu'nun 16 CFR 1610 sayılı alevlenebilir kumaş düzenlemesinde tanımlandığı şekilde, Sınıf I Normal Alevlenebilir olarak sınıflandırılmıştır. Yüksek yoğunluklu ısı kaynaklarını kullanırken standart güvenlik protokollerine uyun.



#### N DİKKAT: Termal yaralanma riskini azaltmak için:

• Primer ambalaj önceden açılmışsa veya hasarlıysa kullanmayın.



## ∱ DİKKAT: Termal yaralanma, hipertermi ya da hipotermi riskini azaltmak icin:

- 3M vücut sıcaklığının sürekli olarak izlenmesini önerir. Sürekli izleme yapılamaması halinde, tepki veremeyen, iletişim kuramayan ve/veya sıcaklığı hissedemeyen hastaları en az 15 dakikada bir veya kurum protokolüne göre izleyin.
- Tepki veremeyen, iletişim kuramayan ve/ veya sıcaklığı hissedemeyen hastaların deri tepkilerini en az 15 dakikada bir veya kurum protokolüne göre izleyin.
- Tedavi hedefine ulaşıldığında, yüksek sıcaklıklar kaydedildiğinde ya da ısınan bölgede advers deri yanıtı oluşursa, hava sıcaklığını ayarlayın veya tedaviyi kesin.

- 3M™ Bair Hugger™ ısıtma battaniyesinin gözenekli tarafını (küçük delikli), hastanın cildine doğrudan temas edecek şekilde hastanın üzerine örtün (Şekil A).
- Mümkün olduğunda, yapışkanlı bant şeridin arkasını çıkarın ve ısıtma battaniyesini hastanın üzerine yapıştırın (Şekil B). Bu, havanın cerrahi alana akışını engeller.

İsteğe bağlı: Etkisini artırmak için ısıtma battaniyesinin üzerine kumaş battaniye ya da



Uyarı: Isıtma battaniyesinin üzerine hasta sabitleme cihazı (emniyet kemeri veya bandı gibi) yerleştirmeyin.



**Uyarı:** İsitma battaniyesini doğrudan dispersif elektrot pedi üzerine yerleştirmeyin.

Bair Hugger ısıtma ünitesi hortumunun ucunu battaniyenin hortum giriş yuvasına takın (Şekil C). Hortum giriş yuvasına sıkı geçmesini sağlamak için çevirerek takın. Hortum takma derinliğini göstermek için, hortum ucunun orta kısmında görsel bir işaret bulunur. Buna uyun. Sağlam bağlantı sağlamak için hortumu destekleyin.



(Nyarı: Hastaları yalnızca ısıtma ünitesinin hortumuyla tedavi etmeyin. Isıtma tedavisi sağlamadan önce hortumu her zaman Bair Hugger ısıtma battaniyesine bağlayın.

#### NOT: Bair Hugger ısıtma battaniyeleri için aşağıda gösterilen özel hususlara bakın

Isıtma tedavisine başlamak için ısıtma ünitesinde istenen sıcaklık ayarını seçin. (Sahip

#### Dikkat: Hasta İzleme Önerileri:

- 3M vücut sıcaklığının sürekli olarak izlenmesini önerir. Sürekli izleme yapılamaması halinde, tepki veremeyen, iletişim kuramayan ve/veya sıcaklığı hissedemeyen hastaları en az 15 dakikada bir veya kurum protokolüne göre izleyin.
- Tepki veremeyen, iletişim kuramayan ve/ veya sıcaklığı hissedemeyen hastaların deri tepkilerini en az 15 dakikada bir veya kurum protokolüne göre izleyin.
- Tedavi hedefine ulaşıldığında, yüksek sıcaklıklar kaydedildiğinde ya da ısınan bölgede advers deri yanıtı oluşursa, hava sıcaklığını ayarlayın veya tedaviyi kesin.
- Kullanılan ısıtma ünitesi modeline göre, ısıtma tedavisini kesmek için üniteyi kapatın ya da bekleme moduna alın. Isıtma ünitesi hortumunu ısıtma battaniyesinden çıkarın ve hastane politikasına göre battaniyeyi atın.

#### Özel Hususlar:

## Model 54200 Çift Yuvalı Torso Battaniyesi, 52200/52301 Üst Gövde Battaniyeleri ve 57000 Cerrahi Erişim Battaniyesi için Çift Yuva

Klinisyen tercihi için iki hortum yuvası mevcuttur. Isitma tedavisi sirasinda kullanılmavan hortum yuvasına çıkarılabilir hortum yuvası kartını yerleştirin (Sekil D).

#### Model 54000/54200 Torso Battaniyeleri, 52200/52301 Üst Gövde Battaniyeleri ve 57000 Cerrahi Erişim Battaniyesi için Kafa Örtüsü.

Hasta entübeyse ve ventile ediliyorsa, kafa örtüsünü hastanın başına ve boynuna örtün (Şekil E); edilmiyorsa örtüyü ısıtma battaniyesinin kanalları arasına, hastanın başından uzağa kıvırın.



Muyarı: Hastanın ventilasyonu mekanik olarak sağlanmıyorsa, ısıtma battaniyesinin veya kafa örtüsünün hastanın başını veya hava yolunu örtmesini engelleyin.

#### Model 52200/52301 Üst Gövde Battaniyeleri (İsteğe bağlı)

Isıtma battaniyesinin üst ve alt kenarlarında ortalanmış olan bağlama şeritlerinin uçlarını çekin. Şişen battaniyenin hastanın üzerinden kaymasını engellemek için bu şeritleri bağlayın. Üst gövde battaniyesini bir kol tablasıyla birlikte kullanmak için, ısıtma battaniyesinin yarısı sargı bandıyla etrafından bağlanabilir veya hastanın altına sıkıştırılabilir (Sekil F).

#### Model 61000 Tam Gövde Cerrahi ve 31500 Çok Erişimli Operasyon Sonrası Battaniyeleri

Erişim panellerini kullanmak için, ısıtma battaniyesinin kenarındaki kesilmemiş şeridi yırtın. Battaniyenin orta kısmındaki bant şeridinin arkasını çıkarın. Erişim panelini geri yapıştırın ve ortaya çıkan banda doğru bastırın. Serbest bırakmak için paneli banttan geri çekin (Şekil G).

#### Model 30500 Göğüs Erisimli Battanive

Hastanın üst gövde bölgesine bakım sağlamak için plastik örtüyü kaldırın (Şekil H).

3M, Bair Hugger ve Bair Hugger logosu, 3M şirketinin ticari markalarıdır.

Kanada'da kullanımı lisansa tabidir.

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# (R) 使用说明

#### 适用范围

3M™ Bair Hugger™ 温度管理系统用于预防和 治疗低温症。此外,如果环境条件可能会导致患 者感觉过热或过冷,则可用温度管理系统为患者 提供舒适的温度。温度管理系统对成人和儿童 患者均适用。

- 未消毒。
- 联邦法律(美国)规定本装置只能由持证的医 疗专业人员进行销售或依其指令使用。

### 禁忌、警告和小心

### 信号词后果释义



-种危险情势,如果未避免的话, 可能导致死亡或严重伤害。



#### 小心:

表示 -种危险情势,如果未避免的话, 可能导致轻度或中度伤害。

#### 

 在行大动脉交叉钳夹期间不得对患者下 肢进行加温。对局部缺血的肢体加温,可 能会导致烫伤。

# 警告: 为降低烫伤风险,请注意以下事项:

- 切勿单独使用 Bair Hugger 加温器软管 对患者进行治疗。提供加温治疗前,应始 终将软管连接到 Bair Hugger 加温毯。
- 切勿让患者躺在加温器软管上。

治疗期间必须有人看管。

- 切勿在加温治疗过程中让加温器软管直接接触患者的皮肤。
- 婴儿、幼儿、儿童和其他脆弱患者在加温
- 长时间加温治疗过程中,切勿让患者处于少量输液无监控状态。
- 不得将加温毯无孔的一面置于患者身上。始终将加温毯打孔的(即有小孔的) 一面直接置于患者之上,接触患者皮肤。
- 在手术室,切勿将该加温毯与 Bair Hugger 500 或 700 系列加温器以外的 任何设备配合使用。
- 切勿在手术室使用 Bair Hugger 200 系列加温器。
- 切勿将 Bair Hugger 800 系列患者可调加温器与任何 Bair Hugger 加温毯配合使用。
- 如果红色温度过高指示灯亮起并听到警报声,必须停止加温治疗。拔掉加温器电源插头并联系有资质的服务人员。
- 切勿将固定装置(即安全带或胶带)置于加温毯之上。
- 切勿将加温毯直接置于分散的电极极板之上。

# 於 警告: 为降低由于给药变化而导致的患者受伤或死亡风险,请注意以下事项:

请勿在透皮药品贴剂之上使用加温毯。

# 於警告。为降低由于妨碍通风而导致的人身伤害风险,请注意以下事项:

如果患者无法实现机械通风,切勿将加温毯或头披覆盖患者的头部或导气管。

# 於警告: 为降低由于患者跌落而导致的可能人身伤害,请注意以下事项:

• 请勿使用加温毯来转移或移动患者。

# ⚠ 小心: 为降低交叉污染风险,请注意以下事项:

该加温毯未经消毒,仅限单个患者使用。在加温毯和患者之间放置床单并不能防止对产品形成污染。

## ⚠ 小心: 为降低火灾风险,请注意以下事项:

 按照消费品安全委员会易燃织物规定 16 CFR 1610 规定,本产品归类为 I 类正 常可燃性。使用高强度热源时要依照标 准安全规程。

## 小心: 为降低烫伤风险,请注意以下事项:

• 如果主要包装曾被打开或破损,不得使

### 小心: 为降低烫伤、高热或温度过低风险,请 注意以下事项:

- 3M 建议持续监测体内温度。如果无法持续监测,每隔 15 分钟或根据医院惯例监测无法自主反应、无法沟通与(或)无温度感觉的患者体温。
- 每隔 15 分钟或根据医院惯例监测无法 自主反应、无法沟通与(或)无温度感觉 的患者皮肤反应。
- 达到治疗目标时、记录高温时或加温部位有不良皮肤反应时,请调节空气温度或终止治疗。

- 将3M™Bair Hugger™加温毯打孔的(即有 小孔的)一面直接置于患者之上,接触患者 皮肤(图 A)。
  - 在适用情况下,撕下粘合带上的背衬膜,将加温毯粘在患者身上(图 B)。这样做可阻止空气流向手术部位。

**可选:**将一条布毯或床单置于加温毯之上以增强效果。

★警告: 切勿将固定装置(即安全带或胶带)置于加温毯之上。

<u>↑</u> 警告: 切勿将加温毯直接置于分散的电极 极板之上。

 将 Bair Hugger 加温器的尾部插入软管端口 (图 C)。扭动软管以确保插入成功。视觉标 记位于环绕软管端中段,其作用是引导软管 的插入深度。支撑软管以确保牢固连接。

↑ 警告: 切勿单独使用加温器软管对患者进行 治疗。提供加温治疗前,应始终将软管连接 到 Bair Hugger 加温毯。

注意: 请参见如下所示 Bair Hugger 加温毯的特 别注意事项。

 在加温器上选择所需温度设置以启动加温 治疗。(请参阅具体加温器型号的操作手册)

↑ 小心:患者监控建议:

- 3M 建议持续监测体内温度。如果无法持续监测,每隔15分钟或根据医院惯例监测无法自主反应、无法沟通与(或)无温度感觉的患者体温。
- 每隔 15 分钟或根据医院惯例监测无法 自主反应、无法沟通与(或)无温度感觉 的患者皮肤反应。
- 达到治疗目标时、记录高温时或加温部位有不良皮肤反应时,请调节空气温度或终止治疗。
- 根据所使用的加温器型号,关闭加温器或切换至待机模式以终止加温治疗。从加温毯上断开加温器软管的连接,根据医院政策弃置加温毯。

#### 特别注意事项:

54200 型双端口躯干加温毯、52200/52301 型上身加温毯和 57000 型手术接触加温毯的双端口

提供两个软管端口以方便临床医生操作。将可移 动的软管端口卡置于加温治疗期间未使用的软 管端口中(图 D)。

54000/54200 型躯干加温毯、52200/52301 型上身加温毯和 57000 手术接触加温毯的头披如果患者正在插管呼吸,将头披置于患者头部和颈部(图 E);否则在加温毯风道之间卷起头披,使之远离患者头部。

▲ 警告: 如果患者无法实现机械通风,切勿将加温毯或头披覆盖患者的头部或导气管。

52200/52301 型上身加温毯(可选)

拉出位于加温毯上下边缘中间的系带拉环。系上这些带子,以防止充气的加温毯从患者身上掀起。若要将上身加温毯与手臂板结合使用,可通过缠绕打包胶带或将其压在患者下来系紧加温毯的一半(图 F)。

61000 型全身手术加温毯和 31500 型多接触 术后加温毯

若要使用接触板,撕开位于加温毯边缘的未切割拉环。取下加温毯中间粘合带上的背衬膜。将接触板折回并按到露出的胶带上。将入路板从胶带上拉开即可释放(图 G)。

30500 型胸部接触加温毯

将透明塑料帘掀起,即可为患者提供上身部位的 护理(图 H)。

3M、Bair Hugger 和 Bair Hugger 徽标是 3M 的商标。

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# 0:15-md-02666-JNE-DTS Doc. 912-1 Filed 10/03/17 Page 255 إرشادات الاستخدام

## دواعي الاستعمال

يهدف نظام إدارة درجة الحرارة ™Bair Hugger من ™MR إلى منع هبوط درجة الحرارة ومعالجته. بالإضافة إلى ذلك، يمكن استخدام نظام إدارة درجة الحرارة لتوفير الراحة الحرارية للمريض في الحالات التي يشعر فيها المرضى بدفء شديد أو برودة شديدة. كما يمكن استخدام نظام إدارة الحرارة مع المرضى من الأطفال والبالغين.

- غير معقمة.
- تحظر القوانين الفيدرالية (في الولايات المتحدة الأمريكية) بيع هذا الجهاز إلا من خلال أحد المتخصصين في شؤون الرعاية الصحية المعتمدين أو بأمر منه.

### موانع الاستخدام والتحذيرات والتنبيهات

## شرح آثار الإشارات المكتوبة

⚠ تحذير:

محدير:
 تشير إلى حالة خطرة قد تؤدي – في حالة عدم
 تجنبها – إلى الوفاة أو إصابة خطيرة.

<u> ۸</u> تنبیه: ''

تشير إلى حالة خطرة قد تؤدي – في حالة عدم تجنبها – إلى إصابة طفيفة أو متوسطة.

# ↑ موانع الاستخدام: للحد من خطر التعرض لإصابة حرارية:

 لا تعرض الأطراف السفلية للحرارة أثناء وضع ملقط الأبهر المعترض. وقد تحدث الإصابة الحرارية في حالة تعرض الأطراف الإقفارية للحرارة.

## 🛕 تحذير: للحد من خطر التعرض لإصابة حرارية:

- لا تعالج المرضى باستخدام خرطوم وحدة التدفئة Bair Hugger فقط. وعليك دائمًا تركيب الخرطوم ببطانية التدفئة من 3M قبل تقديم العلاج بالتدفئة.
  - لا تسمح للمريض بالاضطجاع على خرطوم وحدة التدفئة.
- لا تسمح بملامسة خرطوم وحدة التدفئة لجلد المريض مباشرةً أثناء العلاج بالتدفئة.
  - لا تترك الأطفال حديثي الولادة والرضع والأطفال الصغار وغيرهم من المجموعات المعرضة للخطر بدون مراقبة أثناء العلاج بالتدفئة.
  - لا تترك المرضى الذين يعانون من
     انخفاض التروية بدون مراقبة أثناء العلاج
     بالتدفئة الممتد.
  - لا تضع الجانب غير المثقوب من بطانية التدفئة على المريض. وضع دائمًا الجانب المثقوب (ذا الفتحات الصغيرة) مباشرة على الجزء العلوي للمريض بحيث يلامس جلد المريض.
  - لا تستخدم بطانية التدفئة هذه في غرفة العمليات مع أي جهاز بخلاف وحدة التدفئة Bair Hugger من الفئة 500 أو 700.
  - لا تستخدم الفئة Bair Hugger 200 من وحدة التدفئة في غرفة العمليات.
- ) لا تستخدم الفئة Bair Hugger 800 من وحدة التدفئة القابلة للضبط بواسطة المريض مع أي من بطاطين التدفئة Bair Hugger.
- أوقف العلاج بالتدفئة عند إضاءة مصباح مؤشر فرط درجة الحرارة الأحمر وصدور صوت الإنذار. وافصل وحدة التدفئة، ثم اتصل بفني صيانة مؤهل.
  - لا تضع أداة تأمين المريض (مثل رباط أو شريط السلامة) على بطانية التدفئة.
  - لا تضع بطانية التدفئة مباشرة على ضمادة الإلكترود المشتتة.

# ⚠ تحذير: للحد من خطر إصابة المريض أو وفاته بسبب تعديل تناول الأدوية:

لا تستخدم بطانية التدفئة على رقع العلاج بطريق الأدمة.

تحذير. للحد من خطر الإصابة بسبب التداخل مع التهوية:

 لا تسمح بتغطية بطانية التدفئة أو غطاء الرأس الجراحي رأس المريض أو الحنجرة عند عدم وجود تهوية ميكانيكية للمريض.

ر تحذير: للحد من احتمال التعرض لإصابة بسبب سقوط المريض:

 لا تستخدم بطانية التدفئة لنقل المريض أو تحريكه.

تنبيه: للحد من خطر التلوث الخلطى:

 بطانية التدفئة هذه ليست معقمة ومصممة للاستخدام بواسطة مريض واحد "فقط". ولا يؤدي وضع ملاءة بين بطانية التدفئة والمريض إلى تلوث المنتج.

🧥 تنبيه: للحد من خطر نشوب الحريق:

 هذا المنتج مصنف باعتباره من الفئة I القابلة للاشتعال العادية وفقًا لتعريف لوائح الأنسجة القابلة للاشتعال بلجنة سلامة المنتجات الاستهلاكية، 16 CFR 1610. فاتبع بروتوكولات السلامة القياسية عند استخدام مصادر الحرارة عالية الكثافة.

ي تنبيه: للحد من خطر التعرض لإصابة حرارية:

 لا تستخدم العبوة إذا تم فتحها مسبقًا أو حال تعرضها للتلف.

ر تنبيه: للحد من خطر التعرض لإصابة حرارية أو فرط درجة الحرارة أو انخفاض درجة الحرارة:

- توصي 3M بالمراقبة المستمرة لدرجة الحرارة الأساسية. وفي حالة غياب المراقبة المستمرة، راقب درجة حرارة المرضى الذين يعجزون عن التفاعل و/أو التواصل و/أو الذين لا يمكنهم الإحساس بدرجة الحرارة بحد أدنى كل 15 دقيقة أو وفقًا للبروتوكول الجهازي.
  - وفي حالة غياب المراقبة المستمرة، راقب درجة حرارة المرضى الذين يعجزون عن التفاعل و/أو التواصل و/أو الذين لا يمكنهم الإحساس بدرجة الحرارة بحد أدنى كل 15 دقيقة أو وفقًا للبروتوكول الجهازي.
- قم بتعديل درجة حرارة الهواء أو إيقاف العلاج عند تحقيق الهدف العلاجي أو في حالة تسجيل درجات حرارة متصاعدة أو في حالة وجود استجابة أديمية عكسية في المنطقة التي تمت تدفئتها.

### الإرشادات

- ُ. ضع الجانب المثقوب ببطانية التدفئة Bair ™Hugger (الجانب ذو الفتحات الصغيرة) مباشرةً على الجزء العلوي للمريض بحيث يلامس جلد المريض (الشكل أ). TM من 3M
  - أزل التغليف عن الشريط اللاصق وألصق بطانية التدفئة على المريض (الشكل ب) إذا أمكن ذلك. حيث يمنع ذلك دخول الهواء باتجاه موقع العملية الجراحية.

**اختياري:** ضع بطانية واحدة من القماش أو ملاءة على بطانية التدفئة لزيادة فاعليتها.

∠ تحذير: لا تضع أداة تأمين المريض (مثل رباط أو شريط السلامة) على بطانية التدفئة.

 أي تحذير: لا تضع بطانية التدفئة مباشرة على ضمادة الإلكترود المشتتة.

ركب طرف خرطوم وحدة التدفئة Bair في منفذ الخرطوم (الشكل ج). واستخدم حركة اللف لضمان الملاءمة المحكمة. يوجد مؤشر ظاهر حول القطاع الأوسط بالخرطوم لتوجيه عمق إدخال الخرطوم. قم بدعم الخرطوم لضمان تركيبه بأمان وإحكام.

تحذير: لا تعالج المرضى باستخدام خرطوم وحدة التدفئة فقط. وعليك دائمًا تركيب الخرطوم ببطانية التدفئة من 3M قبل تقديم العلاج بالتدفئة.

## ملاحظة: راجع الاعتبارات الخاصة لبطاطين Bair Hugger الموضحة أدناه.

حدد إعداد درجة الحرارة الذي تريده بوحدة التدفئة لبدء العلاج بالتدفئة. (راجع دليل المشغل الخاص بطراز وحدة التدفئة)

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توصي 3M بالمراقبة المستمرة لدرجة الحرارة الأساسية. وفي حالة غياب المراقبة المستمرة، راقب درجة حرارة المرضى الذين يعجزون عن التفاعل و/أو التواصل و/أو الذبن لا يمكنهم الإحساس بدرجة الحرارة بُحد أُدنَى كُل 15 دقيقة أو وفقًا للبروتوكول الجهازي.

وفى حالة غياب المراقبة المستمرة، راقب درجة حرارة المرضى الذين يعجزون عن التَّفَاعل وَ/أُو التُّواصُّل و/أُوَّ الذِّبِن لاَّ يمكنهم الإحساس بدُرجة الحرارة بُحد أُدنى كُل 15 دقيقة أو وفقًا للبروتوكول الجهازي.

قم بتعديل درجة حرارة الهواء أو إيقاف العلاج عند تحقيق الهدف العلاجي أو في حالة تسجيل درجات حرارة متصاعدة أو في حالة وجود استجابة أديمية عكسية في المنطقة التي تمت تدفئتها.

وبناءً على طراز وحدة التدفئة المستخِدمِة، أوقف الوحدة أو ضعها في وضع الاستعداد أو أوقف العّلاج بالتّدفئة. افصّل خرطوم وحدة التدفئة من بطانية التدفئة وتخلص من البطانية وفقًا لسياسة المستشفى.

#### اعتبارات خاصة:

المنفذ المزدوج للطراز 54200 المنفذ المزدوج لبطانية الْجُذَّعَ، بطاَّطِّين الجزء العلوي 52301/52200 وبطانية الوصول الجراحي 57000

يوجد منفذان للخرطوم حسب تفضيل الطبيب ٱلسريري. فضّع بطاقة منفذ الخرطوم القابلة للإزالة في منفذ الخَّرطومَّ غير المستخدم أثناء العلاج بالتدفئة

الجذع، وبطاطين الجزء العلوي

52301/52200 وبطانية الوصّول الجراحي 57000

في حالة تنبيب المريض أو تعريضه للتهوية، شُع غطاء الرأس الجراحي على رأس المريض ورقبته (الشكل هـ)، وإلاً، فاثنِ غطاء الرأس الجراحي بين قنوات بطانية التدفئة، بُعيدًا عن رأسَ المريضَّ.

**مَحِدَير:** لا تسمح بتغطية بطانية التدفئة أو غطاء الرأسُّ الجراحي رأس المريضُ أو الحنجرةُ عند عدم وجود تهوية ميكانيكية للمريض.

## الطرز 52200/52301 من بطانيات الجزء العلوى من الجسم (اختياري)

اسحب الرباط الشريطي، مع توسطه على طول الحواف العلوية والسفلية ببطانية التدفئة. واربط هذه الأربطة لمنع ابتعاد البطانية المنفوخة عن المريض. لاستخدام بطانية الجزء العلوي مع لوحة ذراع واحدة، يمكن ربط نصف بطانية التدفئة بلف شريط حولها أو طيها أسفل المريض (الشكل و).

# الطراز **61000** الجراحي للجسم بالكامل والبطاطين متعددة الوصول ما بعد الجراحة **31500**

لاستخدام لوحات الوصول، مزق اللسان غير المقطوع عند حافة بطانية التدفئة. قم بإزالة التغليف عن الشريط للاصق الواقع في وسط البطانية. قم بطي اللوحة للخلف واضغط عليها في اتجاه الشريط المكشوف. اسحب اللوحة بعيدًا عن الشريط لتحريرها (الشكل ز). الطراز 30500 لبطانية الصدر

ارفع غطاء الراس الشفاف لتوفير الرعاية لمنطقة الجزء العلُّوي من جسم المريض (الشَّكُلُّ ح).

3M وmair Hugger وشعار Bair Hugger علامات تجارية لشركة 3M.

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# **EXHIBIT DX5**

TO DECLARATION OF BENJAMIN W. HULSE IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SAMSUN LAMPOTANG, PH.D.





Case Report
Volume 4 Issue 1 – May 2017
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# Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient



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#### Introduction

Forced air warming (FAW) devices are used in the operating room to helpmaintain normothermia during anesthesia and prevent complications of hypothermia. Proper use involves connecting the hose of the warming unit to a disposable blanket with a perforation pattern that evenly distributes heat across the patient's body. Multiple studies have shown the efficacy of FAW devices to be better than other widely used interventions such as circulating water mattresses [1]. However, as with most medical interventions there is a potential for complications with FAW devices. We present the case of a FAW device that malfunctioned after it became wet, depositing black soot on the patient.

## **Case Report**

A 67 year old male patient with a history of hypertension, dyslipidemia, and lung cancer presented for a robotic-assisted left upper lobectomy. The patient was taken to the operating room where standard ASA monitors were applied. General anesthesia was induced, and the airway was secured with a 35 French left double lumen tube. A radial arterial line and addition IV lines were placed, after which the patient was positioned in the right lateral decubitus position. The patient's initial bladder temperature was 35.7°C. A FAW blanket was applied to the patient's lower body, and the heating device was set to 43°C. During the procedure, the patient's temperature decreased to 35.0°C and recovered to 35.8°C by the end of surgery. While closing the chest, the line isolation monitor alarm was heard and was investigated. A few minutes later smoke was noticed in the field, and the drapes were removed to identify the source. No flames were seen, and no obvious source of smoke was identified. Then, black punctate spots were noted on the sheets and the patient's lower extremities (Figure 1). Upon investigation, the black spots were soot deposited on the patient in the pattern of the perforation holes of the FAW blanket. The soot was wiped off the patient, and there was no injury to the patient. The blanket itself was dry, but the warming unit was sitting in irrigation thatspilled from the surgical field.



**Figure 1:** Black punctate spots were noted on the sheets and the patient's lower extremities.

### Discussion

The Food and Drug Administration and Anesthesia Patient Safety Foundation discourage "hosing" [2-3], defined as the misuse of FAW devices by applying the hose directly to the patient or to a non-inflatable blanket. This misuse has resulted in various reports of first to third degree burns [4-6], including a reported amputation due to muscle necrosis. In our case, however, the FAW device was properly utilized with the hose attached to an inflatable blanket. Our institutional biomedical service evaluated this incident and device and concluded that the air-intake on the bottom of the unit entrained irrigation into the device, causing a short circuit within the unit. This electrical short created smoke inside the device, which was then blown out through the hose and deposited as soot through the perforation holes in the inflatable blanket. The unit was removed from service and returned to the manufacturer.

This is a near-miss case that could easily have resulted in a fire or electrical shock. The use of line isolation monitors is meant to decrease the risk of electrical shock in the operating room (OR). Common electrical circuits outside of the OR consist of a grounded system where an individual could be electrocuted by completing the electrical circuit. To provide additional safety in the OR, the isolated electrical system is ungrounded and requires two faults in order to cause electrocution [7]. When the

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first fault occurs, the line isolation monitor will alarm. Electrical equipment should then be unplugged in reverse sequence until the alarm stops, which indicates the cause of the first fault. In this case, the FAW device was identified as the cause.

Documented complications from FAW use include an increased incidence of surgical site infections and some instances of burns due to misuse as mentioned above [4-6]. However, to our knowledge, electrical issues have not been reported. In order to prevent similar events and improve OR safety, we now attach our FAW devices to an elevated platform to ensure the device does not contact fluid on the floor.

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